

## POLICY

It is the policy of Florida Health Care Plan, Inc. (FHCP) to manage certain high risk or high cost medications through a Prior Authorization program or a Step Therapy.

## PURPOSE

Prior Authorization and Stepped Care are tools in a process to assist in the proper implementation of medication use. **This policy does not supersede FHCP Medicare Part D coverage criteria and Medicare Part D PA policy which is listed elsewhere. Medicare Part B PA and Step are not listed in this policy.**

### Process for Prior Authorization Request

- Prior Authorization for a Medication may be requested by the member, or prescribing physician or a member's authorized representative verbally or in writing by contacting the FHCP Central Referrals Department.

FHCP Central Referral Department will gather clinical information to be evaluated. A clinical pharmacist with Doctor of Pharmacy degree will perform the final determination. Appeals are reviewed by a Utilization Management Physician for final determination.

- For standard requests, FHCP notifies the requesting physician, member or members' representative of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 days for commercial members after receipt of the request or 72 hours for Medicare members after receipt of the request.
- Medications which are provided and administered by a health care professional incident to a visit are generally part B (unless self-administered greater than fifty percent of the time). If a medication is provided by a pharmacy and administered by a physician, it may be Part D. Further clarification can be found at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/determine.pdf>
- For expedited requests, FHCP notifies the requesting physician, member or member's authorized representative' representative of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request and supporting clinical documentation. Should FHCP require additional information or documentation an additional 48 hours will be allowed to obtain the

information and evaluate for a determination. Under no circumstances will an expedited request exceed 72 hours.

- Approved prior authorizations must be renewed by the member, or prescribing physician or a member's authorized representative verbally or in writing through the FHCP Central Referrals Department prior to expiration date for continued coverage.
- FHCP Central Referrals Department notifies the requesting Physician, Member or Member's representative of a favorable or an adverse Prior Authorization determination in writing. All adverse determination notices will include the appropriate instructions on how to file an Appeal.
- All non-formulary medications are not covered. A prior authorization is required for any exceptions.
- When a Request is for a Prior Authorization Medication is denied FHCP will;
  1. Specify reason for the denial in easily understandable language.
  2. Refer to the guideline, protocol, benefit provision or other criterion upon which the decision is based.
  3. Notify the member and requesting physician they may request a copy of any criterion used to make the decision.
  4. Provide member and requesting physician with a description of appeal rights, including the right to submit written comments, documentation or other information relevant to the appeal and the timeframes for deciding appeals.
- Provide member with a description of the expedited appeal process for urgent pre-service or urgent concurrent denials. Once a prior authorization request has been approved, coverage will be authorized for up to 12 months for most medications.

However, certain generic medications may be covered indefinitely at discretion of the clinical reviewer. An enrollee is not required to re-request an approval to continue using the prescription drug, as long as all of the following conditions are met:

- The member's prescribing physician continues to prescribe the drug.
- The drug continues to be considered safe and effective for treating the member's disease or medical condition.
- The member continues to remain eligible under the plan.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**SUMMARY OF CHANGES FROM PREVIOUS VERSION**

**Update Humira**

**Add Entresto**

**Update Stelara**

**Update Kevzara**

**Update Actemra**

**Update Ocrevus**

**Update Revlimid**

**Update Sodium Oxybate(generic Xyrem)**

**Add Strensiq**

**Add Lisdexamfetamine**

**Add Sunosi**

**PROCEDURE BY MEDICATION (See Attachment 1)**

**Table of Contents**

Abilify Maintena (Aripiprazole injection) J0401 ..... 1

Abraxane (paclitaxel protein bound)-J9264 ..... 2

Actemra (tocilizumab)-J3262 ..... 3

Actimmune (interferon gamma-1b) ..... 4

Adcetris (brentuximab vedotin)-J9042 ..... 5

Adcirca-Generic Only (tadalafil)..... 6

Adempas (riociguat)..... 7

Afinitor Generic Only (Everolimus) ..... 8

Aimovig (ereumab) injection ..... 9

Akynzeo (netupitant-palonosetron) tablet..... 11

Alecensa (alectinib)..... 12

Alimta (pemetrexed) J9305 ..... 13

Amitiza (lubiprostone)-Generic only..... 14

Ampyra GENERIC ONLY (dalfampridine)..... 15

Anadrol (Oxymetholone) ..... 16

Aptiom (eslicarbazepine) ..... 17

Retacrit..... 18

Arcalyst (riloncept)..... 19

Arzerra (ofatumumab) J9303..... 20

Augmentation therapy for Alpha-1 Antitrypsin Deficiency (Aralast/Prolastin) J0256 ..... 21

Zirabev (Bevacizumab-bvzr) Q5118 ..... 22

Avonex (Interferon Beta-1a)..... 23

Axert (almotriptan) ..... 24

Azilect (rasagiline mesylate) Generic Only ..... 25

Banzel (rufinamide)-Generic Only ..... 26

Baqsimi (glucagon) nasal powder ..... 27

Bavencio (Avelumab) J9023..... 28

Berinert [C1 Esterase Inhibitor (Human)] J0597..... 29

Betaseron (Interferon Beta-1b) ..... 30

Blenoxane (Bleomycin) J9040..... 31

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Blinicyto (Blinatumomab) J9039..... 32

Boniva Infusion (Ibandronate) J1740..... 33

Bosulif (bosutinib)..... 34

Botox/Xeomin (botulinum toxin) J0585 J0588 ..... 35

Budesonide EC capsules 3mg (generic entocort) ..... 36

Bydureon/BCISE/Byetta (Exenatide) Step Therapy Drug – Not Prior Authorization..... 37

Caprelsa (vandetanib)..... 38

Carbaglu (carglumic acid)..... 39

Cayston (aztreonam for inhalation)..... 40

Cerezyme (imiglucerase)..... 41

Cesamet (nabilone)..... 42

Cometriq (cabozantinib) ..... 43

Cotellic (cobimetinib)..... 44

Cubicin GENERIC only (Daptomycin) J0878 ..... 45

Cuprimine(Penicillamine) Generic..... 46

Cyramza (ramucirumab) J9308..... 47

Daraprim (pyrimethamine)..... 48

Darzalex (daratumumab) j9145 ..... 49

Denavir(peniciclovir)..... 50

Diabetic Test strips (other than Ascensia Products)..... 51

Dibenzylamine (phenoxybenzamine) ..... 52

Diclofenac Topical 3% (Generic Solaraze)..... 53

Dificid (fidaxomicin) ..... 54

Dimethyl Fumarate (Generic Tecfidera) ..... 55

Doxepin topical (generic Zonalon)..... 56

Doxil/Lipodox (Doxorubicin liposomal) Q2050..... 57

Dronabinol (geosacinarinol) ..... 58

Elaprase (idursulfase) J1743 ..... 59

Elitek (rasburicase)J2783 ..... 60

Emend (Aprepitant) capsules..... 61

Emgality (galcanezumab) injection..... 62

Empliciti (elotuzumab) J9176..... 64

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Enbrel (etanercept).....	65
Entresto (Sacubitril/valsartan).....	66
Enspryng (satralizumab) .....	66
Entyvio (vedolizumab) J3380 .....	68
Generic flolan (epoprostinil).....	69
Erbix (cetuximab) J9055 .....	70
Ergomar (ergotamine tablets) .....	71
Erivedge (vismodegib capsules).....	72
Eucrisa (crisaborole)- STEP THERAPY DRUG- NOT PRIOR AUTHORIZATION .....	73
Exelderm (sulconazole nitrate).....	74
Exjade (Deferasirox) Generic Only .....	75
Fanapt (Iloperidone).....	76
osaconazolepanobinostat).....	76
Fentanyl patch (generic Duragesic)/ Fentanyl Citrate Lozenge (Generic Actiq) .....	77
Ferriprox (deferiprone)-Generic Only.....	78
Fetzima (levomilnacipran) .....	79
Finacea (Azelaic Acid) .....	80
Firazyr (icatibant)-Generic .....	81
Firmagon (degarelix).....	82
Fosrenol-Generic (lanthanum carbonate) .....	83
Frova (frovatriptan)-Generic Only .....	84
Fusilev (levoleucovorin) J0641.....	85
Fycompa (perampanel).....	86
Gammagard (IVIG) J1569.....	87
osaconazoleobinutuzumab) J9301 .....	87
Geodon injection (ziprasidone) J3486 .....	88
Gilenya (Fingolimod) Generic Only.....	89
Gilotrif (Afatinib).....	90
Halaven (eribulin mesylate) J9179.....	91
Halog cream (Halcinonide)-Generic Only .....	92
Hepatitis C Direct Acting Antivirals Mavyret .....	93
HADLIMA Biosimilar Humira (adalimumab) .....	94

**Medications Requiring Prior Authorizations**

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

Humulin U-500 (insulin) .....	95
Ibrance (palbociclib).....	96
Iclusig (ponatanib) .....	97
Idhifa (enasidenib) .....	98
Imbruvica (ibrutinib) .....	99
Imfinzi (durvalumab) J9173 .....	100
Imlygic (talimogene laherparepvec) .....	101
Increlex (mecasermin) .....	102
Inlyta (axitinib) .....	103
Invega Sustenna (Paliperidone injection) J2426.....	104
Iressa (gefitinib) .....	105
IVIG- Gammagard, Privigen, Octogam, Flebogam, Gammunex, Gammar, Gammaplex.....	106
Ixempra (ixabepilone) J9207.....	107
Jakafi (ruxolitinib) .....	108
Januvia (Sitagliptin).....	109
Jevtana (cabazitaxel) J9043 .....	110
Kadcyla (ado-trastuzumab) J9354 .....	111
Kalydeco (ivacaftor) .....	112
Kevzara (sarilumab) .....	113
Keytruda (pembrolizumab) J9271 .....	114
Kineret (anakinra) .....	115
Kuvan (sapropterin)-Generic Only .....	116
Kynamro (mipomersen) .....	117
Kyprolis (carfilzomib) J9047 .....	118
Lenvima (lenvatinib) .....	119
Letairis Generic Only (ambrisentan).....	120
Levulan (aminolevulinic acid) .....	121
Lidocaine patches (generic Lidoderm).....	122
Linzess (linaclotide).....	123
Livalo (pitavastatin).....	124
Lokelma (Sodium zirconium cyclosilicate) .....	125
Lonsurf (trifluridine and tipiracil).....	126

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

osaconaza (olaparib)..... 126

Mekinist (trametinib)..... 127

Movantik (Naloxegol)..... 128

Mozobil (plerixafor) J2562 ..... 129

Multaq (dronedarone) ..... 130

Myrbetriq (mirabegron)..... 131

Omnipod/ Omnipod Dash..... 132

Nebupent (osaconazol isothionate) nebulized-Generic..... 133

Nerlynx (neratinib)..... 134

Neupro (rotigotine)..... 135

Nexavar Generic only(sorafenib) ..... 136

Nicotrol (Nicotine replacement)..... 137

Ninlaro (ixazomib)..... 138

Nisoldipine (generic Sular) ..... 139

Noxafil Geosaconazoleposaconazole) ..... 140

Nucala (mepolizumab)..... 141

Nucynta ER (tapentadol)..... 142

Nuedexta (Dextromethorphan/quinidine) ..... 143

Nulojix (belatacept) J0485 ..... 144

Ocrevus (ocrelizumab) J2350..... 145

Odomzo (sonidegib)..... 146

Omnitrope (somatotropin) ..... 147

Onfi (clobazam) -Generic Only..... 148

Onglyza (Saxagliptin) Kombiglyze (Saxagliptin/Metformin)- Step Therapy ..... 149

Opsumit (macitentan)..... 150

Opdivo (nivolumab) J9299 ..... 151

Orencia (Abatacept) J0129 ..... 152

Orenitram (treptostinil) ..... 153

Orfandin (nitisinone)..... 154

Orilissa/Oriahnn (elagolix, elagolix +estradiol/norethindrone) ..... 155

Oxandrin (Oxandrolone) ..... 156

Oxymorphone ER (generic Opana ER) ..... 157



**Medications Requiring Prior Authorizations**

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

Panretin (alitretinoin) .....	158
Perjeta (pertuzumab) J9306 .....	159
Pirfenidone.....	160
Pomalyst (pomalidomide).....	161
Prolia (Denosumab) J0897 .....	162
Promacta (eltrombopag) .....	163
Pulmicort Respules (Budesonide) Generic Only .....	164
Pulmozyme (Dornase Alfa) .....	165
QTERN (Saxagliptin/Dapagliflozin)- Step Therapy .....	166
Quinine.....	167
QVAR (beclomethasone) inhaler .....	168
Radicava (edaravone) J1301 .....	169
Rapaflo(sildenafil) Generic Only .....	170
Rebif (Interferon Beta-1a).....	171
Repatha (evolocumab).....	172
Generic Remodulin (treprostinil).....	173
Renflexis (infliximab-abda) Q5104.....	174
Revlimid (Lenalidomide) -Generic Only .....	175
Riluzole (generic rilutek) .....	176
Risedronate STEP Therapy .....	177
Risperdal Consta (Risperidone injection) J2794 .....	178
Ruxience (rituximab) Q5119 .....	179
Rozlytrek (entrectinib) .....	180
Rydapt (midostaurin).....	181
Samsca (tolvaptan) Generic Only.....	182
Sandostatin LAR (Octreotide) .....	183
Saphris (asenapine) Generic Only.....	184
Sensipar (cinacalcet) -Generic Only .....	185
Sildenafil citrate 20mg (generic Revatio).....	186
Silenor 3 mg (doxepin) Generic Only .....	187
Simponi (golimumab).....	188
Soliris (eculizumab) J1300.....	189

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Sprycel (dasatinib) ..... 193

Stelara (ustekinumab) J3357 ..... 194

Stivarga (Regorafenib) ..... 195

Strensiq (Asfotase)..... 196

Sunosi (solriamfetol)..... 198

Sustol (granisetron) extended-release injection J1627 ..... 198

Sutent (sunitinib)-Generic..... 199

Sylatron (peg-interferon alpha 2b)..... 200

Sylvant (siltuximab) J2860 ..... 201

Symlin (Pramlintide)..... 202

Synagis (palivizumab)..... 203

Synarel (nafarelin)..... 204

Synera (lidocaine and tetracaine patch)..... 205

Tafinlar (dabrafenib) ..... 206

Tagrisso (osimertinib) ..... 207

Tarceva (erlotinib)-Generic..... 208

Targretin (Bexarotene) Generic Only..... 209

Tasigna (nilotinib) ..... 210

Generic Tasmar (tolcapone) ..... 211

Tazorac (tazarotene)-Generic Only..... 212

Tecentriq (atezolizumab) J9022..... 213

Generic Tekturna (aliskiren) STEP THERAPY- DRUG NOT PRIOR AUTHORIZATION..... 214

Tepezza (teprotumumab) ..... 215

Tetrabenazine (generic xenazine)..... 216

Thalomid (Thalidomide)..... 217

Thyrogen (Thyrotropin alpha)..... 218

Tracleer (bosentan)..... 219

Tramadol ER..... 220

Trelegy Ellipta..... 221

Tretinoin (Generic Retin A) ..... 222

Tretinoin capsules (generic Vesanoïd)..... 223

Trintellix (vortioxetine) ..... 224

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Trisenox (arsenic trioxide)..... 225

Tykerb (lapatinib) -Generic ..... 226

Tymlos (abaloparatide)..... 227

Tysabri (natalizumab) J2323 ..... 228

Tyzeka (Telbivudine) ..... 229

Vectibix (Panitumumab) J9303 ..... 230

Velcade (bortezomib) J9044 ..... 231

Velphoro (sucroferric oxyhydroxide) ..... 232

Venclexta (venetoclax)..... 233

Ventavis (iloprost) nebulized ..... 234

Victoza (liraglutide)..... 235

Covered for use in established cardiovascular disease for patients on a Statin who have failed metformin  
Visudyne (Verteporfin) ..... 235

Voriconazole (generic Vfend) ..... 237

Votrient (Pazopanib)..... 238

White blood cell colony stimulating factors Granix/Leukine/Zarzio/Nivastym (filgrastim-aafi),  
Zarxio-Filgrastim-sndz, Fulphila, Udenyca, Ziextenzo Leukine- sargramostim) ..... 239

Xalkori (crizotinib)..... 243

Vyvanse (Lisdexamfetamine) ..... 244

Xartemis (Oxycodone and Acetaminophen) ER Tablets ..... 245

Xeljanz (tofacitinib) ..... 246

Xgeva (denosumab) J0897 ..... 247

Xolair (omalizumab) J2357..... 248

Xtandi (enzalutamide)..... 249

Xyrem (Sodium Oxybate) Generic Only ..... 250

Yervoy (ipilimumab) J9228 ..... 251

Zaltrap (ziv-aflibercept) J9400 ..... 252

Zavesca (miglustat) Generic Only ..... 253

Zejula (niraparib)..... 254

Zelboraf (vemurafenib)..... 255

Zolinza (Vorinostat)..... 256

Zortress (everolimus) capsules ..... 257

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Zydelig (idelalisib) Tablets.....	258
Zyflo (zileuton) .....	259
Zykadia (ceritinib) capsules.....	260
Zyprexa Relprevv (Olanzapine injection) .....	261
Zytiga (Abiraterone) GENERIC Only .....	262

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Abilify Maintena (Aripiprazole injection) J0401**

Exchange Pharmacy	<b>X</b>	Medical Commercial	<b>X</b>
Commercial Pharmacy	<b>X</b>	Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Aripiprazole is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Failure of oral aripiprazole and lurasidone
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Abraxane (paclitaxel protein bound)-J9264**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Abraxane is an anti-neoplastic agent indicated to treat metastatic breast cancer, advanced non-small cell lung cancer, and metastatic pancreatic adenocarcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Actemra (tocilizumab)-J3262**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- .
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications must be prescribed by a rheumatologist.
- Must fail Simponi, Kevzara, Adalimumab, Enbrel, Renflexis for overlapping indications

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Actimmune (interferon gamma-1b)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Actimmune is indicated to prevent infection in Chronic Granulomatous disease, and also delay the time to progression with severe malignant osteopetrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, antibiotic failure for chronic granulomatous disease.
- Limited to specialist trained in management of prescribed condition.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Adcetris (brentuximab vedotin)-J9042**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- ADCETRIS is an antibody-drug conjugate FDA indicated to treat relapsed or refractory Hodgkin lymphoma and systemic anaplastic large cell lymphoma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Adcirca-Generic Only (tadalafil)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Adcirca is indicated for treatment of pulmonary arterial hypertension (WHO group 1).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Pulmonary hypertension must be diagnosed by right heart catheterization.
- Evaluation, EKG, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- This medication is contraindicated in patients using organic nitrates either regularly or intermittently.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Adempas (riociguat)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Adempas is indicated to treat Pulmonary Arterial Hypertension (PAH) and Chronic Thromboembolic Pulmonary Hypertension (CTPH).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Failure of tadalafil and ambrisentan
- Prescriber must be a cardiologist or pulmonologist
- Diagnosis of PAH supported by right heart catheterization.
- Failure of sildenafil and bosentan.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Afinitor Generic Only (Everolimus)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Afinitor is an oral tyrosine kinase inhibitor indicated to treat several malignancies.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Prescribing restricted to oncology.

**Aimovig (erenumab) injection**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Aimovig is a anti-CGRP antibody indicated for prophylaxis of Episodic and Chronic Migraines

**Episodic Migraines**

**Aimovig** will be approved based upon **all** of the following criteria:

(1) Diagnosis of episodic migraines with **both** of the following:

- (a) Less than 15 headache days per month
- (b) Patient has 4 to 14 migraine days per month

**-AND-**

(2) Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:

- (a) Amitriptyline
- (b) atenolol, metoprolol, nadolol, propranolol, or timolol
- I Venlafaxine (Effexor/Effexor XR)

**AND**

(3) Medication will not be used in combination with an oral CGRP antagonist or inhibitor

**Authorization will be issued for 6 months.**

**2. Reauthorization**

a. **Aimovig** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with an oral CGRP Antagonist.

**Authorization will be issued for 12 months.**

**B. Chronic Migraines**

**1. Initial Therapy**

**Aimovig** will be approved based upon **all** of the following criteria:

(1) Diagnosis of chronic migraines with **both** of the following:

- (a) Greater than or equal to 15 headache days per month continued.
- (b) Greater than or equal to 8 migraine days per month

**-AND-**

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:

(a) Amitriptyline

(b) atenolol, metoprolol, nadolol, propranolol, or timolol(e) Venlafaxine (Effexor/Effexor XR)

**-AND-**

(3) Medication will not be used in combination with an oral CGRP antagonist

**Authorization will be issued for 6 months.**

**2. Reauthorization**

a. **Aimovig** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with an oral CGRP Antagonist.

**Authorization will be issued for 12 months.**

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Akynzeo (netupitant-palonosetron) tablet**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Akynzeo is indicated for chemotherapy induced nausea and vomiting
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must have failed generic ondansetron, generic granisetron (oral/IV), aprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines)

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Alecensa (alectinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Alecensa is indicated to treat patients with ALK+ metastatic Non-Small cell lung cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Prescriber must be an oncologist



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Alimta (pemetrexed) J9305**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Alimta is indicated to treat metastatic or locally advanced non-squamous NSCLC and Mesothelioma
- Medical history and studies are reviewed in Referrals and if approved will notify the physician

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Prescriber must be an oncologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Amitiza (lubiprostone)-Generic only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Amitiza is indicated for chronic constipation and irritable bowel syndrome
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber must be a gastroenterologist
- Must have failed lactulose and Miralax

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ampyra GENERIC ONLY (dalfampridine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Ampyra is indicated to treat patients with multiple sclerosis who have walking disability.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- c. Diagnosis of multiple sclerosis AND patient is ambulatory (able to walk at least 25 feet) AND patient has walking impairt.
- l.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Anadrol (Oxymetholone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Anadrol is an anabolic steroid indicated to treat various types of anemia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications

Medical history and information reviewed by referrals. Coverage will be response to previous treatments, and the consideration of other therapeutic options (ESAs, B12/folate, iron).

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Aptiom (eslicarbazepine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Aptiom is an anti-convulsant indicated for adjunctive treatment of partial seizures.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by neurology for adjunctive treatment of seizures.
- Failure of Oxcarbazepine and carbamazepine.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Retacrit**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- ESAs are used to treat anemia related to Chronic Kidney Disease, Chemotherapy, Myelodysplastic Syndrome, Antiviral therapy. Prior authorization is required for pharmacy coverage of medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Pharmacy coverage criteria as follows:

- FDA approved indications
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.
- Patient must have adequate iron stores (ferritin  $\geq$  100 ng/ml, transferrin saturation  $>$ 20%).
- Hemoglobin for initiation and maintenance must be compliant with current FDA labeling.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Arcalyst (rilonacept)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Arcalyst is indicated to treat Cryopyrin Associated Periodic Syndromes (CAPS).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- Diagnosis of CAPS and Documentation of disability due to the condition, failure of anakinra, and nsaid.
- Prescribing limited to immunologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Arzerra (ofatumumab) J9303**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Arzerra is indicated to treat chronic lymphocytic leukemia (CLL)
- Medical history and studies are reviewed in Referrals and if approved will notify the physician

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Failure of rituximab
- Prescriber must be an oncologist



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Augmentation therapy for Alpha-1 Antitrypsin Deficiency (Aralast/Prolastin) J0256**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- This is an infusion therapy for patients with severe obstructive disease due to Alpha-1 Antitrypsin deficiency.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications.
- Patient must be a non-smoker.
- Serum Concentration of Alpha-1 Antitrypsin must be less than 11micromoles/L.
- Must have a high-risk AAT deficiency phenotype (PiZZ, PiZ (null) or Pi (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11 uM/L.)
- Documented progressive COPD.
- FEV<sub>1</sub> between 35%-65% predicted.
- Currently using Long acting bronchodilator and Oral or inhaled corticosteroids.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zirabev (Bevacizumab-bvzr) Q5118**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zirabev an anti-VEGF monoclonal antibody used to treat metastatic, recurrent, or locally advanced cancers.
- Ophthalmic uses such as wet AMD and macular edema will be covered without clinical review for Zirabev or Avastin.

Criteria for coverage (for oncology indications) as follows:

- FDA Approved Uses
- Off-Label indications will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Avonex (Interferon Beta-1a)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Avonex is an interferon indicated to treat multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of glatiramer and Dimethyl Fumarate for new starts

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Axert (almotriptan)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Axert is a 5-ht agonist indicated for treatment of migraine headaches.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- This medication requires failure of rizatriptan and sumatriptan prior to coverage.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Azilect (rasagiline mesylate) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Azilect is a monoamine oxidase inhibitor type B indicated for treatment of Parkinson’s disease
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Must have failed recent trial Levodopa/Carbidopa.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Banzel (rufinamide)-Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Banzel is indicated for treatment of Lennox Gastaut syndrome. Prior authorization only applies to existing members who are new starts on the drug.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written/ordered by a Neurologist for seizures through referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Baqsimi (glucagon) nasal powder**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Baqsimi is indicated for severe hypoglycemia where patient is unable to eat, drink or follow commands.
- Baqsimi is intranasal but does not need to be inhaled, patient does not need to be conscious for Baqsimi to be administered.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- Ordered by an endocrinologist.
- Limit of 1 device per dispensing, two per year.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Bavencio (Avelumab) J9023**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- BAVENCIO is a programmed death ligand-1 (PD-L1) blocking antibody indicated treatment of advanced or metastatic cancers
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Beriner [C1 Esterase Inhibitor (Human)] J0597**

Exchange Pharmacy	<b>X</b>	Medical Exchange	
Commercial Pharmacy	<b>X</b>	Limited Distribution	
Step Therapy		Quantity Limit	

- BERINERT is a plasma-derived C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by an immunologist, allergist or hematologist
- Must have C1INH deficiency demonstrated by labs (C1INH and C4 labs)
- Must not be taking medications that can exacerbate the frequency and/or severity of hereditary angioedema (HAE) attacks including estrogens and ACE inhibitors.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Betaseron (Interferon Beta-1b)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Betaseron is an interferon indicated to treat multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of Dimethyl Fumarate and glatiramer or fingolimod for new starts

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Blenoxane (Bleomycin) J9040**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Blenoxane is an antineoplastic and can be used as a sclerosing agent for malignant pleural effusions.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications.
- Must be prescribed by oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Blinicyto (Blinatumomab) J9039**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Blincyto is a Bispecific monoclonal antibody targeting CD-19, it is FDA indicated for second-line treatment for Philadelphia chromosome-negative relapsed or refractory acute lymphoblastic leukemia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Boniva Infusion (Ibandronate) J1740**

Exchange Pharmacy		Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Boniva IV is indicated for treatment of Osteoporosis. It is a parenteral bisphosphonate given by IV infusion every 3 months.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Failure of zoledronic acid.
- Not for use in patients with severe renal impairment (Crcl<30 ml/min).

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Bosulif (bosutinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Bosulif is indicated for treatment of Ph+ CML after failure of a first line tyrosine kinase inhibitor.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Restricted to hematology/oncology.
- Failure of imatinib.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Botox/Xeomin (botulinum toxin) J0585 J0588**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Botulinum toxin is approved for medical and cosmetic purposes. FHCP covers this medication only for medically necessary purposes and is approved for:
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Cervical dystonia, not responsive to physical therapy.
- Blepharospasm that interferes significantly with vision.
- Headache not responsive to preventive and acute therapy by Neurology for at least 16 weeks.
- This information is sent to the Referrals Department.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Budesonide EC capsules 3mg (generic entocort)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Entocort is an oral steroid capsule that has low bioavailability. Entocort is indicated for mild to moderately active Crohn’s disease involving the ileum and/or the ascending colon and the maintenance of clinical remission in mild-to moderate Crohn’s disease involving the ileum and/or the ascending colon for up to 3 months.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Written by a gastroenterologist
- Approved referrals will be for a maximum of 6 months.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Bydureon/BCISE/Byetta (Exenatide) Step Therapy Drug – Not Prior Authorization**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Byetta/Bydureon are injectable anti-diabetic agent used to treat Type 2 Diabetes. Bydureon/ Byetta are indicated for adjunctive use with a sulfonylurea and/or metformin.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- Step therapy after trial of metformin.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Caprelsa (vandetanib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Caprelsa medication indicated for treatment of metastatic medullary thyroid cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Prescriber must be a Hematologist/Oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Carbaglu (carglumic acid)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Carbaglu is indicated to treat NAGS deficiency.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cayston (aztreonam for inhalation)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Cayston is indicated for treatment of pulmonary pseudomonas in cystic fibrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications.
- Failure or intolerance to Tobramycin nebulized solution

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cerezyme (imiglucerase)**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Cerezyme is indicated for the treatment of Gaucher’s disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Indicated for the treatment of a patient with Type 1 Gaucher’s disease with anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cesamet (nabilone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Cesamet is a cannabinoid indicated to prevent nausea and vomiting related to chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of ondansetron AND palonosetron AND aprepitant

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cometriq (cabozantinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Cometriq is indicated for treatment of metastatic medullary thyroid cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications.
- Prescriber must be a Hematologist/Oncologist.
- Combination use with other tyrosine kinase inhibitors is excluded.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cotellic (cobimetinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Cotellic is indicated for treatment of BRAF+ metastatic or unresectable melanoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must be prescribed by Oncologist.
- Must be used in combination with Zelboraf.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Cubicin GENERIC only (Daptomycin) J0878**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Cubicin is an IV antibiotic indicated for the treatment of resistant gram positive bacterial infections. FHCP will participate in a program to reduce the risk of further development of drug resistant strains of bacteria by encouraging appropriate use.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Patient is identified as having an infection caused by VRE (Vancomycin Resistant Enterococcus) or VRSA (Vancomycin Resistant Staph Aureus) by culture and sensitivity; and linezolid is not a therapeutic option OR
- Patient has a skin or soft tissue infection caused by cMRSA and resistant/PT allergic to other generically available oral agents or combinations which may be used to treat cMRSA (Sulfamethoxazole/TMP, Rifampin, Clindamycin, Doxycycline) and patient is allergic to vancomycin and Zyvox. OR

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cuprimine(Penicillamine) Generic**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Cuprimine is indicated for treatment of Rheumatoid arthritis, Wilsons Disease and cystinuria.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Written by a Rheumatologist, or Neurologist, or Urologist or Hepatologist.
- Coverage for Rheumatoid Arthritis requires failure of a TNF Agent, and A JAK inhibitor or Abatacept.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Cyramza (ramucirumab) J9308**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Cyramza is a VEGF-2 antagonist indicated for treatment of NSCLC, Gastric and GE junction adenocarcinoma, and metastatic colorectal cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Prescribed by a hematologists/oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Daraprim (pyrimethamine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Daraprim is used to treat toxoplasmosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Toxoplasmosis.
- Patient must have failed recent trial of combination of inhaled corticosteroids AND long acting beta Agonist AND inhaled anti-cholinergic.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Darzalex (daratumumab) j9145**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

DARZALEX is a CD38-directed cytolytic antibody indicated:

- in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy
- in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double refractory
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Denavir(peniciclovir)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Denavir is an antiviral used to treat oral HSV.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications.
- failure of acyclovir

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Diabetic Test strips (other than Ascensia Products)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Test strips other than Ascensia products are covered only when incompatible with an insulin pump, or if patient has a severe visual impairment.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Dibenzylamine (phenoxybenzamine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Dibenzylamine is used to treat pheochromocytoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Diagnosis of Pheochromocytoma.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Diclofenac Topical 3% (Generic Solaraze)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- This medication is a topical NSAID indicated for treatment of Actinic Keratosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Diagnosis of actinic keratosis.
- Prescribed by a dermatologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Dificid (fidaxomicin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Dificid is an oral antibiotic indicated to treat clostridium difficile related diarrhea.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications.
- Failure of vancomycin 6 week taper dose.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Dimethyl Fumarate (Generic Tecfidera)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Dimethyl fumarate is an oral DMT (disease modifying treatment) indicated to treat relapsing remitting multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Doxepin topical (generic Zonalon)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- This medication is a topical tricyclic for indicated for short term treatment of pruritus in patients with atopic dermatitis.

Criteria for coverage as follows:

- Failure of topical steroids and hydroxyzine.
- FDA approved indication.
- Approved only for short term use.
- Prescribed by a dermatologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Doxil/Lipodox (Doxorubicin liposomal) Q2050**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

DOXIL is an anthracycline topoisomerase II inhibitor indicated for:

- Ovarian cancer  
After failure of platinum-based chemotherapy.
  
- AIDS-related Kaposi Sacoma  
After failure of prior systemic chemotherapy or intolerance to such therapy.
  
- Multiple Myeloma  
In combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy
  
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Dronabinol (ge58osaconarinol)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Dronabinol is indicated to treat HIV/Cancer related Cachexia and chemotherapy induced nausea and vomiting.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- For cachexia, patient must fail megestrol acetate.
- For nausea and vomiting patient must fail Ondansetron and Emend.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Elaprase (idursulfase) J1743**

Exchange Pharmacy		Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Elaprase is an enzyme replacement therapy indicated to treat Hunter’s Syndrome.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Limited to specialist trained in management of prescribed condition.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Elitek (rasburicase)J2783**

Exchange Pharmacy		Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Elitek is an enzyme replacement therapy indicated to treat/prevent hyperuricemia due to chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Emend (Aprepitant) capsules**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Emend is used as part of a three day regimen for chemotherapy induced nausea and vomiting (CINV) of moderate to highly emetogenic Chemotherapy treatments, and Post-Operative Nausea and Vomiting.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient must have failed Zofran.
- A pre-packaged three-day course of this medication will be approved per each co-pay incidental to a chemotherapy treatment cycle.
- Medication will be approved through referrals when written by Oncology.

**Emgality (galcanezumab) injection**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Emgality is an anti-CGRP antibody indicated for prophylaxis of Episodic and Chronic Migraines, and Cluster Headaches

**Episodic Migraines**

**Emgality 120 mg** will be approved based upon **all** of the following criteria:

(1) Diagnosis of episodic migraines with **both** of the following:

- (a) Less than 15 headache days per month
- (b) Patient has 4 to 14 migraine days per month

**-AND-**

(2) Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:

- (a) Amitriptyline
- (b) atenolol, metoprolol, nadolol, propranolol, or tilol
- (e) Venlafaxine (Effexor/Effexor XR)

**AND**

(3) Medication will not be used in combination with an oral CGRP antagonist or inhibitor

**Authorization will be issued for 6 months.**

**2. Reauthorization**

a. **Emgality 120 mg** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with an oral CGRP Antagonist.

**Authorization will be issued for 12 months.**

**B. Chronic Migraines**

**1. Initial Therapy**

**Emgality 120 mg** will be approved based upon **all** of the following criteria:

(1) Diagnosis of chronic migraines with **both** of the following:

- (a) Greater than or equal to 15 headache days per month continued.

- (b) Greater than or equal to 8 migraine days per month

**-AND-**

## **Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:

- (a) Amitriptyline
- (b) atenolol, metoprolol, nadolol, propranolol, orlmolol
- (e) Venlafaxine (Effexor/Effexor XR)

**-AND-**

(3) Medication will not be used in combination with an oral CGRP antagonist

**Authorization will be issued for 6 months.**

### **2. Reauthorization**

a. **Emgality 120 mg** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with an oral CGRP Antagonist.

**Authorization will be issued for 12 months.**

### **C. Episodic Cluster Headache**

#### **1. Initial Therapy**

a. **Emgality 100 mg** will be approved based upon **all** of the following criteria:

(1) Diagnosis of episodic cluster headache

**-AND-**

(2) Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

**-AND-**

(3) Medication will not be used in combination with an oral CGRP antagonist.

**Authorization will be issued for 6 months.**

#### **2. Reauthorization**

a. **Emgality 100 mg** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with an oral CGRP antagonist

**Authorization will be issued for 12 months**

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Empliciti (elotuzumab) J9176**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

EMPLICITI is a SLAMF7-directed immunostimulatory antibody indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Enbrel (etanercept)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Enbrel is a biologic disease modifying agent, indicated for treatment of RA, JRA, PSA, Plaque psoriasis (see Guidelines for Enbrel (Attachment 3))
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- Must be written by Rheumatology, Dermatology or Specialist trained in management of prescribed condition.
- For RA Patient must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS (3 month trial in past 6 months).
- For Ankylosing Spondylitis PT must fail MTX or sulfasalazine and 2 NSAIDS within past 6 months.
- For Plaque Psoriasis patient must fail MTX or Soriatane and topical therapy.
- For Psoriatic Arthritis Patient must fail adequate trial of MTX or LEF in past 6 months.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Entresto (Sacubitril/valsartan)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Entresto is a medication used for treatment of Heart Failure
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- For Heart Failure with reduced ejection fraction ( $\leq 40\%$ )
  - For initiation
    - eGFR  $\geq 30$ ml/min and  $K^+ < 5.0$  meq/l for initiation
    - Patient has NYHA Class II-IV symptoms
    - Approve for 3 months initially
  - For continuation
    - Member is at target dose approve for 12 months
    - Member is below Entresto target dose THEN
      - Approve for 3 months if member is tolerating dose but has not had a titration attempt and SBP  $> 100$

OR

Approve for 12 months if member has failed titration attempt or SBP  $< 100$

- For Heart Failure with preserved ejection fraction
  - For initiation
    - Patient has an ejection fraction  $\leq 55\%$
    - NYHA Class II-IV symptoms
    - Currently taking an SGLT-2 inhibitor
    - eGFR  $> 30$  ml/min
    - Approve for 3 months initially
  - For continuation
    - Member is at target dose approve for 12 months
    - Member is below Entresto target dose THEN
      - Approve for 3 months if member is tolerating dose but has not had a titration attempt and SBP  $> 100$

OR

- Approve for 12 months if member has failed titration attempt or SBP  $< 100$

**Enspryng (satralizumab)**

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Enspryng is a monoclonal antibody indicated to treat neuromyelitis optica spectrum disorder
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

a. Member meets **ALL** of the following - documentation must be provided:

i. Anti-aquaporin-4 (AQP4) antibody positive disease

ii. **ONE** of the following:

1. Member has a history of at least 2 relapses in the past 12 months

2. Member has a history of at least 3 relapses in the past 24 months with at least 1 relapse in the previous 12 months

iii. Member has an Expanded Disability Status Scale (EDSS) score less than or equal to 7

iv. Member had an inadequate response or contraindication to corticosteroids

IV

**AND**

a. **ONE** of the following:

1. Member had an inadequate response to an adequate trial of **ONE** or more of the following:

a. azathioprine

b. mycophenolate mofetil

c. methotrexate

**AND**

b. Member had an inadequate response to rituximab

**AND**

c. Treatment is prescribed by or in consultation with a neurologist

**INITIAL** Approval duration: 60 days for all indications, continuation based on clinical improvement.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Entyvio (vedolizumab) J3380**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Entyvio is indicated for the treatment of Crohn’s disease, ulcerative colitis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Must be written by a gastroenterologist and had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) and an anti-inflammatory (5-asa, sulfasalazine, balsalazide, mesalamine) And Renflexis. Requires a 3 month trial in past 6 months



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Generic flolan (epoprostinil)**

Exchange Pharmacy		Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- epoprostinil is a prostacyclin analog indicated to treat primary pulmonary arterial hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by a pulmonologist or cardiologist.
- Pulmonary hypertension must be diagnosed by heart catheterization, Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- Patient must be a WHO class III or IV and fail combination ambrisentan and tadalafil.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Erbix (cetuximab) J9055**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

Erbix is indicated for squamous cell carcinoma of the head and neck and K-Ras wild type EGFR-expressing metastatic colorectal cancer

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ergomar (ergotamine tablets)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Ergomar is indicted for treatment of vascular headaches.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of two formulary 5HT- antagonists (triptans).
- Must be prescribed by Neurologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Erivedge (vismodegib capsules)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Erivedge is indicated for treatment of metastatic or locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and are not candidates for radiation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber is a hematologist/oncologist.
- Patient has Metastatic basal cell cancer, or recurrent basal cell cancer, or who are not candidates for surgery and not candidates for radiation.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Eucrisa (crisaborole)- STEP THERAPY DRUG- NOT PRIOR AUTHORIZATION**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy	<b>X</b>	Limited Distribution	
		Quantity Limit	

- Eucrisa is a Step Therapy Medication indicated for treatment of mild to moderate atopic dermatitis.

Criteria for coverage as follows:

- Covered after failure of topical steroid when clinically appropriate.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Exelderm (sulconazole nitrate)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Exelderm is a topical antifungal indicated for tinea pedis tinea corporis, and tinea versicolor.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient has failed 2 generically available topical anti-fungals in past 6 months.
- Approved by referrals based on pharmacy history.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Exjade (Deferasirox) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Exjade is an oral medication used to treat iron overload typically in patients receiving chronic RBC transfusions.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Fanapt (Iloperidone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Fanapt is indicated to treat schizophrenia.
- Prior authorization only applies to existing members who are new starts on the drug.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of aripiprazole, or lurasidone

**Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new start.76osaconazolepanobinostat)**

- Farydak is indicated to treat multiple myeloma in patients who have received at least two therapies including Velcade and an immunomodulatory agent.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications.
- Must be written by an oncologist.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Fentanyl patch (generic Duragesic)/ Fentanyl Citrate Lozenge (Generic Actiq)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Fentanyl patch is a long acting opioid analgesic indicated for moderate to severe chronic pain.
- Fentanyl Citrate Lozenge is a short acting opioid indicated for cancer breakthrough pain
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Fentanyl citrate lozenges approved after failure of hydromophone IR and morphine IR and oxycodone IR
- Approved when written/ordered by an Oncologist or Pain Management through referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ferriprox (deferiprone)-Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Ferriprox is indicated to treat iron overload secondary to transfusion dependence. This medication is only on the Medicare and Exchange formularies.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber restricted to Oncologist/hematologist.
- Failure of deferasirox
- Failure of Desferal.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Fetzima (levomilnacipran)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Fetzima is an antidepressant (enantiomer of milnacipran) used to treat major depressive disorder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure or intolerance to two generically available anti-depressants in past 6 months.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Finacea (Azelaic Acid)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Finacea is indicated to treat mild to moderate rosacea.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on failure of metronidazole and an oral tetracycline.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Firazyr (icatibant)-Generic**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Firazyr is indicated to treat acute attacks of Hereditary Angioedema
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician. Limited to two per month.

Criteria for coverage as follows:

- FDA approved indications

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Firmagon (degarelix)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Firmagon is indicated to treat advanced prostate cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician. Limited to two per month.

Criteria for coverage as follows:

- FDA approved indications
- Written by oncology or urology

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Fosrenol-Generic (lanthanum carbonate)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Fosrenol is a non-calcium based, chewable, phosphate binder indicated to manage hyperphosphatemia in ESRD.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Patient has ESRD.
- Patient has elevated calcium on phosphate binders, or not a candidate for calcium based phosphate binders based on KDOQI guidelines.
- Prescribed by a nephrologist
- Not covered in combination with other non-calcium based phosphate binders.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Frova (frovatriptan)-Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Frova is a 5-ht agonist indicated for treatment of migraine headaches.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- This medication requires failure of rizatriptan and sumatriptan prior to coverage.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Fusilev (levoleucovorin) J0641**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Fusilev is a folate analog indicated for: use in combination with fluorouracil-based regimens, high-dose methotrexate rescue, impaired methotrexate elimination and folic acid antagonist overdose.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Leucovorin must be unavailable in the United States

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Fycompa (perampanel)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Fycompa is an anti-convulsant indicated for adjunctive treatment of partial seizures.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Written by a neurologist for treatment of seizures.
- Failure of Levetiracetam, topiramate, and lamotrigine

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Gammagard (IVIG) J1569**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- This product is used for immunodeficiency disorders as well as certain autoimmune conditions, including: Hypogammaglobinemia, Kawasaki disease, ITP.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

**Approval will be based on compliance with most current Medicare NCD or LCD coverage criteria for IVIG. This information is sent to the Referrals**

**Department 87 (osaconazoleobinutuzumab) J9301**

- Gazyva is indicated to treat follicular lymphoma and chronic lymphocytic leukemia
- Medical history and studies are reviewed in Referrals and if approved will notify the physician

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Prescriber must be an oncologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Geodon injection (ziprasidone) J3486**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Geodon is a psychotropic medication. Prior authorization only applies to existing members who are new starts on the drug.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Gilenya (Fingolimod) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Gilenya is an oral medication indicated for treatment of relapsing remitting multiple sclerosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Must be written by a neurologist
- Covered for patients who have failed a trial of glatiramer and Dimethyl Fumarate

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Gilotrif (Afatinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Gilotrif is an oral tyrosine kinase inhibitor indicated to treat NSCLC with the genetic tumor markers of exon 19 deletion and exon 21 substitution.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

Prescribing restricted to oncology.

Patient must have NSCLC mutations consistent with FDA label.

Test for T790M mutation if previously on a TKI inhibitor

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Halaven (eribulin mesylate) J9179**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- HALAVEN is a microtubule inhibitor indicated for the treatment of patients with metastatic breast cancer Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Halog cream (Halcinonide)-Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Halog is a topical high potency steroid
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on failure of Diflorasone and Betamethasone.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Hepatitis C Direct Acting Antivirals Mavyret**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

Mavyret is the exclusive and preferred DAA for treatment of HCV in chronically infected non-cirrhotic and compensated cirrhotic patients for genotypes 1-6. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Mavyret is the preferred DAA for all genotypes, other DAAs will be covered on a case by case basis if Mavyret use is not supported by current FDA indication or HCV guidelines based on patient specific characteristics

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**HADLIMA Biosimilar Humira (adalimumab)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Adalimumab is indicated for the treatment of confirmed rheumatoid arthritis (RA), plaque psoriasis (PP), Psoriatic Arthritis (PSA) Crohn’s disease (CD), ulcerative colitis (UC), Hydradenitis suppurativa, uveitis. This is non-preferred for commercial, ACA, and Exchange.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Must be written by Rheumatology, Dermatology or Specialist trained in management of prescribed condition.
- Dosing for indication is the FDA approved dose, off label dosing for an indication is not covered.
- In Commercial and ACA plans- Patient must fail a preferred agent Enbrel, Simponi, in areas of overlapping indication (RA, PSA,PP, UC,AS), for IBD Disease must fail Renflexis, Simponi Azathioprine, and 6 Mercaptopurine.
- For hidradenitis suppurativa must have moderate to severe disease and have failed recent trial 8 to 12 week trial in past month of oral clindamycin and rifampin or doxycycline/Minocycline, Infliximab, AND oral retinoid (acitretin or isotretinoin) unless contraindicated in the past 6 months.
- For Uveitis patient must fail 8-12 week trial of methotrexate

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Humulin U-500 (insulin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Humulin U 500 is used to treat insulin resistant diabetes mellitus.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Initiation restricted to endocrinology.
- Insulin requirements of >200 units/day

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ibrance (palbociclib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Ibrance is a CDK 4/6 inhibitor indicated for first-line/second line treatment of metastatic ER+/HER- breast cancer used in combination with an aromatase inhibitor
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by Hematologist/oncologist.
- Diagnosis Metastatic ER+ HER- Breast cancer.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Iclusig (ponatanib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Iclusig is a tyrosine Kinase inhibitor indicated to treat Chronic Myelogenous Leukemia. Coverage will be based on failure of first or second line TKI for CML or presence of T350I mutation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by Hematologist/oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Idhifa (enasidenib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Idhifa is indicated for treatment of relapsed or refractory AML in patients with an IDH2 mutation as detected by an approved test
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Prescriber must be a Hematologist/Oncologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Imbruvica (ibrutinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Imbruvica is a BTK inhibitor used to treat B cell lymphomas. It is indicated for relapsed refractory chronic lymphocytic leukemia and Mantle Cell Lymphoma, and first line CLL.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Must be prescribed by Hematologist/oncologist.
- FDA approved indications
- NCCN supported use with evidence rating 2a or greater

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Imfinzi (durvalumab) J9173**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for urothelial carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Imlygic (talimogene laherparepvec)**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

IMLYGIC is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Increlex (mecasermin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Increlex is indicated to treat short stature in patient with primary Insulin like Growth Factor deficiency, and patients with neutralizing antibodies to HGH.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.

Must be prescribed by a Pediatric Endocrinologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Inlyta (axitinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Inlyta is an oral tyrosine kinase inhibitor indicated for advanced renal cell carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Prescribing restricted to oncology.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Invega Sustenna (Paliperidone injection) J2426**

Exchange Pharmacy	<b>X</b>	Medical Commercial	<b>X</b>
Commercial Pharmacy	<b>X</b>	Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Invega Sustenna is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Failure of oral aripiprazole, paliperidone and risperidone
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Iressa (gefitinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Iressa is indicated to treat non-small cell lung cancer with EGFR mutation exon 19 deletion or Exon 21 substitution mutations.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must be prescribed by Oncologist
- T790 mutation testing when indicated i.e. previously treated with a TKI inhibitor

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**IVIG- Gammagard, Privigen, Octogam, Flebogam, Gammunex, Gammar, Gammaplex**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- This product is used for immunodeficiency disorders as well as certain autoimmune conditions, including: Hypogammaglobinemia, Kawasaki disease, ITP.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Approval will be based on compliance with most current Medicare NCD or LCD coverage criteria for IVIG. This information is sent to the Referrals Department.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ixempra (ixabepilone) J9207**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

Ixempra, a microtubule inhibitor, in combination with capecitabine is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.

Ixempra as monotherapy is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Jakafi (ruxolitinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Jakafi is an oral JAK inhibitor indicated for treatment of intermediate to high risk myelofibrosis including primary myelofibrosis, polycythemia vera, myelofibrosis, and essential thrombocythemia myelofibrosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Not used in combination with lenalidomide/thalidomide, other JAK or TKI inhibitors
- Prescriber is a hematologist/oncologist.
- Continuation in therapy will require 50% reduction in baseline spleen size, or 35% reduction in spleen volume, or a 50% reduction in baseline Myelofibrosis symptom score.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Januvia (Sitagliptin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Januvia is an oral anti-diabetic agent used to treat Type 2 Diabetes (DPP-IV inhibitor).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient must be on maximal doses of Metformin and Sulfonylurea or other combination therapy if metformin contraindicated for at least 6 months, or have intolerance/contraindication.
- Failure of Onglyza.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Jevtana (cabazitaxel) J9043**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

Jevtana is a microtubule inhibitor indicated for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kadcyla (ado-trastuzumab) J9354**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Kadcyla is an Antibody Drug Conjugate (ADC) indicated for second line treatment of HER+ metastatic breast cancer.
- Medical history and studies are reviewed in Referrals and will notify provider after coverage determination.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on failure of prior taxane and Herceptin (Trastuzumab).

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kalydeco (ivacaftor)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Kalydeco is an oral medication indicated to treat Cystic fibrosis patients with specific genetic mutations in the CFTR gene.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient must have an FDA approved mutation.
- Must be prescribed by a Pulmonologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kevzara (sarilumab)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Kevzara is an injectible Il-6 antagonist indicated for rheumatoid arthritis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Coverage is limited to Rheumatoid arthritis
- Must fail a preferred specialty agent (Enbrel, Xeljanz, Simponi)
- Most have clear documentation of moderate to severe rheumatoid arthritis

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Keytruda (pembrolizumab) J9271**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Keytruda is a PD-1 inhibitor indicated treatment of several cancer types.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kineret (anakinra)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Kineret is a biologic agent indicated for treatment of rheumatoid arthritis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient must fail two anti-TNF biologics and Xeljanz

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kuvan (sapropterin)-Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Kuvan is indicated to treat Phenylketonuria (PKU).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, Dietary compliance, and the consideration of other therapeutic options.
- PKU level above 6mg/dl (360 micromoles/L).
- Prescribing limited to specialist trained in management of PKU.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kynamro (mipomersen)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Kynamro is indicated to treat Homozygous Familial hypercholesterolemia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Genetic confirmation that patient is HoFH.
- Failure of Statin, Ezetimibe, and PCSK-9 therapy.
- Continuation of Kynamro after 3 month trial based on LDL reduction of at least 25% while on therapy.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Kyprolis (carfilzomib) J9047**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

Kyprolis is a proteasome inhibitor that is indicated:

- in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy one of which containing bortezomib
- as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Lenvima (lenvatinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Lenvima is a tyrosine kinase inhibitor indicated for several cancers
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Letairis Generic Only (ambrisentan)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Letairis is an endothelin receptor antagonist used to treat WHO group 1 pulmonary arterial hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Pulmonary hypertension must be diagnosed by heart catheterization.
- Patient must have failed or have contraindication to sildenafil.
- Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- Approved referrals will initially provide coverage for 12 weeks. Continuation of coverage will be determined by an improvement of an objective test of exercise (6 minute walk) from baseline. Follow-up documentation must be submitted for continuation of coverage.
- Patients who have had an initial positive response based the 12 week follow-up will be approved for an additional 6 months, and re-evaluation with documentation will be required every 6 months for continuation of coverage.
- This medication is contraindicated in pregnancy, those of childbearing ability who are not using contraception,

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Levulan (aminolevulinic acid)**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Levulan is indicated for actinic keratosis of the scalp or face.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA Approved indications
- by Dermatology or Plastic Surgery only.
- This information is sent to the Referrals Department.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Lidocaine patches (generic Lidoderm)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- This is a transdermal formulation of lidocaine indicated for treatment of post-herpetic neuralgia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Coverage will be based on failure or contraindications of other therapies including failure of Gabapentin.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Linzess (linaclotide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Linzess is indicated for chronic constipation and irritable bowel syndrome.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- failure of lactulose and Miralax.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Livalo (pitavastatin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Livalo is an HMG-CoA reductase inhibitor (statin).
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage requires failure of pravastatin and rosuvastatin.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Lokelma (Sodium zirconium cyclosilicate)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Lokelma is indicated to treat hyperkalemia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Hyperkalemia after discontinuation trial of potassium sparing medications, trial of a loop diuretic if clinically indicated.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Lonsurf (trifluridine and tipiracil)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Lonsurf is indicated to treat patients with metastatic colorectal cancer who have progressed on two to three lines of treatment
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.

**Must be prescribed by an Oncologist126osaconaza (olaparib)**

- Lynparza is used to treat BRCA+ ovarian or breast cancers
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Restricted to Hematology/Oncology.

**Medications Requiring Prior Authorizations**

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

**Mekinist (trametinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Mekinist is a MEK inhibitor indicated to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma and NSCLC
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Patient must have BRAF V600E/K mutation.
- Must be written by an oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Movantik (Naloxegol)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Movantik is a Peripherally Acting Mu Opioid Antagonist (PAMORA) indicated for opioid induced constipation
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Requires failure of lactulose and Miralax.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Mozobil (plerixafor) J2562**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

Mozobil, a hematopoietic stem cell mobilizer, is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Multaq (dronedarone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Multaq is indicated for treatment of atrial fibrillation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must have previously failed or have contraindication to both sotalol and amiodarone.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Myrbetriq (mirabegron)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- This medication is used to treat overactive bladder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of solifenacin, trospium, and Toviaz.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Omnipod/ Omnipod Dash**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Omnipod and Omnipod Dash are covered for Type 1 diabetics who meet MCG (Milliman Coverage Guideline) criteria

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nebupent (133osaconazol isothionate) nebulized-Generic**

Exchange Pharmacy	<b>X</b>		Medical Commercial	
Commercial Pharmacy			Medical Exchange	
Step Therapy			Limited Distribution	
			Quantity Limit	

- Nebupent is an inhaled solution used to treat PCP pneumonia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of topical ketoconazole, econazole, clotrimazole betamethasone, nystatin triamcinolone.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nerlynx (neratinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nerlynx is indicated for extended adjuvant treatment of early stage HER2 breast cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Prescriber must be a Hematologist/Oncologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Neupro (rotigotine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Neupro is a transdermal dopamine agonist indicated for treatment of Parkinson’s disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of Ropinirole and Pramipexole.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nexavar Generic only(sorafenib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nexavar is an oral tyrosine kinase inhibitor indicated to treat Renal cell carcinoma, Hepatocellular carcinoma, and thyroid carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Prescribing restricted to oncology.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nicotrol (Nicotine replacement)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Indicated for smoking cessation therapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Must have previously failed or have contraindication to Bupropion.
- Coverage is approved for 24 weeks of treatment.
- Copayment will be applied per package.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ninlaro (ixazomib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Ninlaro is an oral proteasome inhibitor indicated to treat relapsed or refractory multiple myeloma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must be prescribed by Oncology
- Must have failed bortezomib

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nisoldipine (generic Sular)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nisoldipine is an oral calcium channel blocker used for treatment of hypertension
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of Amlodipine and Diltiazem required for coverage of Nisoldipine, approved by referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Noxafil Ge140(isaconazole/posaconazole)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Noxafil is an anti-fungal indicated for aspergillus and Candida in immunocompromised patients.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Organism must be resistant to itraconazole, voriconazole, and fluconazole.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nucala (mepolizumab)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nucala is an interleukin 5 antagonist indicated for eosinophilic asthma and eosinophilic granulomatosis with polyangiitis and nasal polyps
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.
- Nasal Polyp indication is covered only by exception and will be based on all available treatment options including nebulized sinus treatments and devices

The following criteria must be met for coverage for severe eosinophilic asthma:

- Prescriber must be a pulmonologist or allergist.
- Two or more severe exacerbations in the past 12 months
- Patient must fail 3 months of therapy on maximal indicated doses of Trelegy and Montelukast

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nucynta ER (tapentadol)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nucynta is an opioid analgesic indicated for chronic pain or severe diabetic peripheral neuropathy (DPN).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- For Chronic pain, failure of morphine sulfate, tramadol, and fentanyl patch.
- For DPN must fail an oral opioid and duloxetine.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nuedexta (Dextromethorphan/quinidine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nuedexta is indicated to treat pseudobulbar affect.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications (Not covered for off-label use)
- Prescriber must be a neurologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Nulojix (belatacept) J0485**

Exchange Pharmacy		Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Nulojix is a biologic immunosuppressive anti-rejection agent for kidney transplant.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber must be a nephrologist or transplant specialist.
- Patient must have failure or intolerance to a calcineurin inhibitor.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ocrevus (ocrelizumab) J2350**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of relapsing remitting or primary progressive forms of multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by a neurologist
- For Relapsing Remitting Multiple Sclerosis – must have failed Dimethyl Fumarate or Glatiramer

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Odomzo (sonidegib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Odomzo is an oral oncology agent indicated to treat locally advanced basal cell carcinoma which has recurred following radiation or surgery.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by Oncology

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Omnitrope (somatotropin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Growth Hormone is a pituitary hormone used for endogenous HGH deficiencies
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

Criteria for coverage as follows:

- FDA approved indications
- This information with the lab attached is sent to the Referrals Department.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Onfi (clobazam) -Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Onfi is a benzodiazepine indicated to treat seizures.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of levetiracetam, topiramate, and clonazepam
- Approved when written/ordered by a Neurologist through referrals for new starts.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Onglyza (Saxagliptin) Kombiglyze (Saxagliptin/Metformin)- Step Therapy**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Onglyza is an oral anti-diabetic agent (DPP-IV inhibitor) indicated to treat Type 2 Diabetes.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Trial of Metformin

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Opsumit (macitentan)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Opsumit is indicated for treatment Pulmonary arterial Hypertension (PAH).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of ambrisentan and sildenafil/tadalafil.
- Pulmonary hypertension diagnosed by right heart catheterization.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Opdivo (nivolumab) J9299**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Opdivo is a PD-1 inhibitor used for treatment of several tumor types.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Orencia (Abatacept) J0129**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Orencia is indicated to treat rheumatoid arthritis, JIA, and Psoriatic arthritis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by a rheumatologist.
- Must fail Kevzara, Simponi Aria, Renflexis, adalimumab, and Enbrel for shared indications.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Orenitram (treptostinil)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Orenitram is indicated to treat Pulmonary Arterial Hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Group 1 PAH
- Must be prescribed by a Pulmonologist or Cardiologist.
- Right Heart catheterization to diagnose PAH
- Failure of combination ERA+PDE5 inhibitor, failure of remodulin

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Orfandin (nitisinone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Orfandin is indicated for hereditary tyrosinemia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be prescribed by a specialist experienced in treatment of this disorder.
- Failure of dietary modification

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Orilissa/Oriahnn (elagolix, elagolix +estradiol/norethindrone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Orilissa is indicated for moderate to severe pain due to endometriosis
- Oriahnn is indicated for treatment of heavy menstrual bleeding due to uterine fibroids
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of an NSAID and oral contraceptive/progestin for endometriosis

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Oxandrin (Oxandrolone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Oxandrin is an anabolic steroid indicated for weight gain in cachexia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written by Oncology, through referrals.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Oxymorphone ER (generic Opana ER)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Oxymorphone is an opioid analgesic indicated for moderate to severe chronic pain.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- For Chronic pain, failure of morphine sulfate ER, Methadone, and fentanyl patch.
- QTY limit of 93/month

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Panretin (alitretinoin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Panretin is a retinoid indicated for Kaposi sarcoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of vinblastine

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Perjeta (pertuzumab) J9306**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Perjeta is a monoclonal antibody indicated for first and second line treatment of HER+ metastatic breast cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by Oncology

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Pirfenidone**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Pirfenidone is indicated for idiopathic pulmonary fibrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- Confirmed diagnosis of IPF by high resolution CT or surgical biopsy.
- Prescribed by a pulmonologist

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Pomalyst (pomalidomide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Pomalyst is thalidomide analog used to treat refractory Multiple Myeloma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, Off label use must be supported by NCCN with evidence rating of 2a or greater
- Restricted to Hematology/Oncology.
- Coverage requires failure of Revlimid and Velcade

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Prolia (Denosumab) J0897**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Prolia is a RANK-L ligand antagonist indicated for treatment of osteoporosis and prevention of osteoporosis for patients taking aromatase inhibitors.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Intolerance or contraindication to injectable bisphosphonate required for coverage of Prolia.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

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**Review/Revision: 72**

**Promacta (eltrombopag)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Promacta is indicated to treat ITP and thrombocytopenia secondary to HCV treatment.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient must have chronic ITP and bleed risk, with platelet count less than 30,000, and refractory to IVIG, corticosteroids or splenectomy.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Pulmicort Respules (Budesonide) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- This medication is a respiratory steroid indicated for treatment of asthma in pediatric patient's ages 6 months– 8 years old.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written for patients ages 6 months to 8 years through pharmacy.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Pulmozyme (Dornase Alfa)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Pulmozyme is indicated to reduce pulmonary exacerbation in patients with cystic fibrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by a pulmonologist.
- Patient must have an FVC  $\geq$  40% of predicted value and recurrent pulmonary infections.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**QTERN (Saxagliptin/Dapagliflozin)- Step Therapy**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- QTERN is an oral anti-diabetic agent (DPP-IV inhibitor +SGLT-2) indicated to treat Type 2 Diabetes.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Trial of Metformin

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Quinine**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- This medication is indicated for treatment of malaria.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**QVAR (beclomethasone) inhaler**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- QVAR is an inhaled corticosteroid indicated for asthma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must have failed Arnuity and Flovent for overlapping indications.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Radicava (edaravone) J1301**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- This medication is indicated for amyotrophic lateral sclerosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Rapaflo(silodosin) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- This medication is indicated for benign prostatic hypertrophy
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage requires failure of terazosin, tamsulosin, alfuzosin

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Rebif (Interferon Beta-1a)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Rebif is an interferon indicated to treat multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of glatiramer and Dimethyl Fumarate for new starts

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Repatha (evolocumab)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Repatha is a PCSK-9 inhibitor used to treat hypercholesterolemia. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of rosuvastatin 40mg or atorvastatin 80 and ezetimibe 10mg in combination. Diagnosis of HeFH must be supported by Dutch Lipid Clinic Network criteria. Statin intolerant patients must have had a hydrophilic statin such as rosuvastatin, pravastatin, fluvastatin in the absence of fibrates or other combinations which can increase risk of myopathy or myalgia.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Generic Remodulin (treprostinil)**

Exchange Pharmacy		Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Remodulin is a prostacyclin analog indicated to treat primary pulmonary arterial hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by a pulmonologist or cardiologist.
- Pulmonary hypertension must be diagnosed by heart catheterization, Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- Patient must be a WHO class III or IV and fail combination ambrisentan and tadalafil.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Renflexis (infliximab-abda) Q5104**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Renflexis is indicated for the treatment of Crohn’s Disease and Rheumatoid Arthritis, Ulcerative Colitis, Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- For use in RA must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS (3month trial in past 6 months).
- For use in Ankylosing Spondylitis PT must fail MTX or sulfasalazine and 2 NSAIDS within past 6 months.
- For use in Plaque Psoriasis must fail MTX or acitretin(Soriatane) and topical therapy.
- For Psoriatic Arthritis must fail adequate trial of MTX or LEF in past 6 months.  
For with Crohn’s disease and ulcerative colitis must be written by a gastroenterologist and had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) for maintenance of remission or failure of corticosteroids for induction of remission.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Revlimid (Lenalidomide) -Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	<b>X</b>

- Revlimid is indicated for treatment of Multiple Myeloma, Myelodysplastic syndrome anemia that is transfusion dependent and has 5q deletion karyotype, mantle cell lymphoma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber is a hematologist/oncologist.
- Patient must have failed Aranesp & Procrit for MDS anemia.
- Mantle cell Lymphoma requires failure of two prior treatment regimens one of which being bortezomib.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Riluzole (generic rilutek)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Rilutek is indicated for the treatment of ALS.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Diagnosis is definite or probable ALS by Neurology.
- Symptoms have been present for less than 5 years.
- Vital Capacity is 60% or more of predicted.
- Patient does not have a tracheostomy.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Risedronate STEP Therapy**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy	<b>X</b>	Limited Distribution	
		Quantity Limit	<b>X</b>

- This medication is indicated for Osteoporosis and Osteopenia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure or intolerance to alendronate

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Risperdal Consta (Risperidone injection) J2794**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Risperdal Consta is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Failure of oral aripiprazole and risperidone
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ruxience (rituximab) Q5119**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Ruxience is a CD-20 targeted B-cell depleting biologic.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.
- Rituxan Hycela is not covered

Criteria for coverage (for treatment of malignancies) as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

Criteria for coverage (for treatment of Rheumatoid Arthritis) as follows:

- Patient has failed 2 or more Anti-TNF agents.
- Coverage will be for 1000mg x 2 treatments separated by 2 weeks.
- Retreatment will not be covered sooner than 24 weeks post initial infusion.
- Patient must be on Methotrexate.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Rozlytrek (entrectinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Rozlytrek is a kinase inhibitor indicated for solid tumors with NTRK-Fusions and ROS-1 mutated Non-Small Cell lung cancer
- Medical history, studies, and appropriate confirmatory tests are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Rydapt (midostaurin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Rydapt is a kinase inhibitor indicated to treat AML, MCL, and systemic mastocytosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Samsca (tolvaptan) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Samsca is indicated to treat hyponatremia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Symptomatic hyponatremia (serum sodium <125 mEq/L).
- Failure of demeclocycline and fluid restriction.
- Removal of medications which are associated with hyponatremia if clinically possible.
- Prescribed by nephrology.
- Limited to 30 days of use.
- Initiated under hospital observation.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sandostatin LAR (Octreotide)**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Sandostatin is indicated for acromegaly and severe diarrhea associated carcinoid syndrome or VIP secreting tumors
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Failure of recent 2 month trial of octreotide (non LAR) in past 3 months

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Saphris (asenapine) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Saphris is indicated for treatment of Bipolar Disorder or Schizophrenia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- AND Approved when written/ordered by a Psychiatrist or Neurologist
- AND failure of both quetiapine and aripiprazole

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sensipar (cinacalcet) -Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Sensipar is indicated to treat hyperparathyroidism that is secondary to renal insufficiency or hypercalcemia secondary to parathyroid carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient is identified as having hypercalcemia associated with parathyroid carcinoma OR
- Patient is identified as having hyperparathyroidism secondary ESRD in patient with elevated PTH. Patient must have failed phosphate binders and active Vitamin-D therapy, iPTH must be >300 in dialysis patients.
- Limitations – This medication must be prescribed by Nephrology or Endocrinology or Oncology.
- Exclusions – Not for use in children, pregnancy, seizure disorder.
- This information is sent to the Referrals Department.
- Medicare Part B is patient is ESRD.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sildenafil citrate 20mg (generic Revatio)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Revatio is indicated for the treatment of Primary pulmonary hypertension or pulmonary hypertension related to connective tissue disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Pulmonary hypertension must be diagnosed by heart catheterization.
- Evaluation, EKG, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- This medication is contraindicated in patients using organic nitrates either regularly or intermittently.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Silenor 3 mg (doxepin) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Silenor is indicated for the treatment of insomnia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure of zolpidem, zaleplon, trazadone, temazepam

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Simponi (golimumab)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Covered only for Commercial/Exchange Simponi/is a TNF antagonist indicated for Moderate to severe rheumatoid arthritis, ankylosing spondylitis, active psoriatic arthritis, moderate to severe ulcerative colitis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows in Commercial and Exchange only:

- For use in RA must be written by rheumatology, fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2- nonbiologic DMARDS (3month trial in past 6 months).
- For use in Ankylosing Spondylitis PT must fail MTX or sulfasalazine and 2 NSAIDS within past 6 months.
- For Psoriatic Arthritis must fail adequate trial of MTX or LEF in past 6 months.
- For with ulcerative colitis must be written by a gastroenterologist and had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) and an anti-inflammatory (5-asa, sulfasalazine, balsalazide, mesalamine)



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Soliris (eculizumab) J1300**

Exchange Pharmacy	<b>X</b>	Medical Commercial	<b>X</b>
Commercial Pharmacy	<b>X</b>	Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- This Soliris is a c5 inhibitor used for paroxysmal nocturnal hemoglobinuria, hemolytic uremic syndrome, anti acetylcholine receptor antibody positive myasthenia gravis, anti-aquaporin-4 antibody positive neuromyelitis optica spectrum disorder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

**Paroxysmal Nocturnal Hemoglobinuria (PNH)**

- Flow cytometry to confirm PNH in both red and white blood cells (with at least 5% granulocyte or monocyte clone size) – documentation must be provided
- Member meets **BOTH** of the following:
  - Absolute neutrophil count greater than or equal to 500/mm<sup>3</sup>
  - Platelets greater than or equal to 30,000/mm<sup>3</sup>
- Member’s lactate dehydrogenase (LDH) is elevated (i.e., 1.5 times greater than the upper limit of normal [ULN] as determined by the laboratory performing the test)
- EITHER** of the following:
  - Member’s disease is transfusion-dependent evidenced by 2 or more transfusions in the 12 months prior to eculizumab initiation
  - Member has a history of a major adverse vascular event (MAVE) from thromboembolism (e.g., myocardial infarction, cerebrovascular accident, deep vein thrombosis)

**2. Atypical Hemolytic Uremic Syndrome (aHUS)**

- Diagnosis is supported by **BOTH** of the following (documentation must be provided):
  - No evidence of Shiga toxin-producing E. coli infection - all initial and subsequent tests have been negative for the toxin

ii. ADAMTS-13 level is greater than 5%

b. **ONE** of the following:

i. Member has been vaccinated against meningococcal infection at least 2 weeks prior to therapy initiation

ii. Member has been vaccinated against meningococcal infection less than 2 weeks prior to therapy initiation and will receive prophylactic antibiotics for at least 2 weeks following vaccination

**3. Refractory Generalized Myasthenia Gravis (MG)**

a. Member meets **ALL** of the following - documentation must be provided:

- i. Anti-acetylcholine receptor (AChR) antibody positive disease
- ii. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV
- iii. Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 6

**AND**

1. Member had an inadequate response to at least one year trial of **TWO** of the following immunosuppressants:

- a. azathioprine
- b. cyclosporine
- c. mycophenolate mofetil
- d. tacrolimus
- e. methotrexate
- f. cyclophosphamide

**AND**

2. Member had an inadequate response to at least one year trial of **ONE** immunosuppressant in combination with either chronic IVIG or plasmapheresis

**AND**

3. Member has had a 1 year trial of rituximab

**AND**

4. Treatment is prescribed by or in consultation with a neurologist

**4. Neuromyelitis Optica Spectrum Disorder (NMOSD)**

a. Member meets **ALL** of the following - documentation must be provided:

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

- i. Anti-aquaporin-4 (AQP4) antibody positive disease
  - ii. **ONE** of the following:
    - 1. Member has a history of at least 2 relapses in the past 12 months
    - 2. Member has a history of at least 3 relapses in the past 24 months with at least 1 relapse in the previous 12 months
  - iii. Member has an Expanded Disability Status Scale (EDSS) score less than or equal to 7
  - iv. Member had an inadequate response or contraindication to corticosteroids
- IV

**AND**

- b. Failed **Enspryng (satralizumab-mwge)**

**AND**

- c. **ONE** of the following:
  - 1. Member had an inadequate response to an adequate trial of **ONE** or more of the following:
    - a. azathioprine
    - b. mycophenolate mofetil
    - c. methotrexate
    - d. rituximab
  - 2. Member has a contraindication to **ALL** of the following:
    - a. azathioprine
    - b. mycophenolate mofetil
    - c. methotrexate
    - d. rituximab

**AND**

- d. Treatment is prescribed by or in consultation with a neurologist

INITIAL Approval duration: 60 days for all indications ,continuation based on clinical improvement. Somatuline (lanreotide)

- This medication is used to treat Acromegaly.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Criteria for coverage as follows:

- FDA approved indications
- Prescriber must be an endocrinologist
- Failure of octreotide

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sprycel (dasatinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Sprycel is an oral antineoplastic agent used to treat Philadelphia Chromosome + CML and PH+ ALL
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Covered for treatment failure with imatinib.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Stelara (ustekinumab) J3357**

Exchange Pharmacy	<b>X</b>	Medical Commercial	<b>X</b>
Commercial Pharmacy	<b>X</b>	Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Stelara is indicated for treatment of moderate to severe plaque psoriasis and psoriatic arthritis and Crohn’s disease
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications only at FDA approved doses
- Prescribed by a dermatologist or Rheumatologist.
- Only covered as a medical benefit.
- Notes supporting moderate to severe Plaque psoriasis or Psoriatic arthritis
- For Plaque Psoriasis, recent failure (in past 6 months) of Renflexis, and Enbrel in combination with topical treatment following conventional therapy.
- For Psoriatic Arthritis failure of adalimumab, Renflexis, Enbrel, Xeljanz, and Simponi.
- For Crohns Disease must fail conventional agents AND adalimumab, Renflexis, Entyvio, , AND TNF in combination with a conventional immunosuppressant (when clinically appropriate) with 5-ASA anti-inflammatory.
- For Ulcerative Colitis must fail conventional agents AND adalimumab, Renflexis/Simponi, Entyvio, Xeljanz, AND TNF in combination with a conventional immunosuppressant (when clinically appropriate) with 5-ASA anti-inflammatory.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Stivarga (Regorafenib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Stivarga is an oral tyrosine kinase inhibitor indicated to treat Colorectal cancer and, Hepatocellular carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Prescribing restricted to oncology.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Strensiq (Asfotase)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Strensiq is an enzyme replacement therapy indicated for infantile or pediatric onset hypophosphatasia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows: Must meet ALL of the following criteria:

1. Member is diagnosed with any of the following:

- a. Perinatal/infantile-onset hypophosphatasia (HPP)
- b. Juvenile-onset hypophosphatasia (HPP)

AND

2. Member’s diagnosis of HPP is confirmed by or in consultation with an endocrinologist or a bone and mineral specialist.

AND

3. Member has skeletal abnormalities indicative of HPP – documentation from the medical record must be provided.

- a. Note: Examples of skeletal abnormalities include chest wall deformities, hypomineralized. skeleton, rickets, nonhealing fractures.

AND

4. Member has an alkaline phosphatase (ALP) level below age-adjusted lower limit of normal, while off medications which can lower ALP such as anti- resorptives.

AND

5. Member has a pyridoxal-5’-phosphate (PLP) level greater than two times laboratory’s upper limit, while off vitamin supplementation (2 week washout)

AND

6. Member has an ALPL genetic mutation – laboratory documentation must be provided.

AND

7. Member has an onset of clinical signs and symptoms of HPP prior to 12 years of age – documentation from the medical record must be provided.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

STRENSIQ continued..

AND

8. Strensiq is prescribed by or in consultation with an endocrinologist or a bone and mineral specialist.

AND

9. Dose does not exceed 6 mg/kg/week.

**Initial approval 6 months**

**Continuation of Strensiq meets definition of Medical Necessity for members when the following criteria are met:**

1. Member has demonstrated a clinical improvement in symptoms following initiation of asfotase alfa – documentation from the medical record must be provided

AND

2. Strensiq is prescribed by or in consultation with an endocrinologist or a bone and mineral specialist

3. Dose does not exceed:

a. Perinatal/infantile-onset HPP: 9 mg/kg/week

b. Juvenile-onset HPP: 6 mg/kg/week

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sunosi (solriamfetol)**

Exchange Pharmacy	X	Medical Commercial	X
Commercial Pharmacy	X	Medical Exchange	X
Step Therapy		Limited Distribution	
		Quantity Limit	

- Sunosi is a dopamine and norepinephrine inhibitor indicated for treatment of excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Coverage is limited to indication of Narcolepsy

Criteria for coverage as follows:

- Failure of Modafinil and Armodafinil

**Sustol (granisetron) extended-release injection J1627**

- Sustol is a 5-HT3 receptor antagonist indicated in combination with other antiemetics for chemotherapy induced nausea and vomiting
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must have failed generic ondansetron, generic granisetron (oral/IV), aprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines)

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

**Sutent (sunitinib)-Generic**

- Sutent is an oral tyrosine kinase inhibitor indicated to treat Renal cell carcinoma, Gastrointestinal Stromal Tumors, and pancreatic neuroendocrine tumors.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Prescribing restricted to oncology.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sylatron (peg-interferon alpha 2b)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Sylatron is an adjuvant treatment for metastatic melanoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be used as adjuvant treatment within 84 days of surgical resection in patients with metastatic melanoma with nodal involvement.
- Prescriber must be an oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Sylvant (siltuximab) J2860**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Sylvant is a monoclonal antibody indicated to treat multicentric castleman’s disease in patients who are HIV negative and HHV-8 negative.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written by an oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Symlin (Pramlintide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Symlin is indicated to treat Type 1 and 2 Diabetes. Symlin is indicated for adjunctive treatment of DM with insulin.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber is an endocrinologist.
- Patient is uncontrolled despite optimal insulin utilization with Ha1c between 7%-9%.
- Not for use in patients with gastroparesis.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Synagis (palivizumab)**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Synagis is a monoclonal antibody indicated to prevent Respiratory Syncytial Virus in newborn infants with certain risk factors.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on current AAP guidelines for use of Palivizumab (Synagis).
- Physician must complete [Synagis request form \(Attachment 4\)](#) and Fax or Mail to the Referrals Department.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Synarel (nafarelin)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Synarel is a GNRH analog (intranasal formulation) indicated to treat precocious puberty in children or endometriosis in adults.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written by an endocrinologist or gynecologist.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Synera (lidocaine and tetracaine patch)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodesiccation and shave biopsy of skin lesions
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tafinlar (dabrafenib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Tafinlar is a BRAF inhibitor indicated to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma and NSCLC
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Patient must have BRAF V600E/K mutation.
- Must be written by an oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tagrisso (osimertinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Tagrisso is indicated to treat patients with metastatic non-small cell lung cancer who possess an EGFR mutation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must possess the t790m mutation if being used after progression on an EGFR tyrosine kinase inhibitor.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tarceva (erlotinib)-Generic**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Tarceva is indicated to treat patients with metastatic non-small cell lung cancer who possess an EGFR mutation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Targretin (Bexarotene) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Targretin is indicated for cutaneous T-cell lymphoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by an oncologist.
- Must have failed one prior systemic therapy.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tasigna (nilotinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tasigna is an oral antineoplastic agent used to treat Philadelphia Chromosome + CML
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Covered for treatment failure with imatinib.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Generic Tasmar (tolcapone)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tasmar is indicated for adjunctive treatment of Parkinson’s disease when used adjunctively with levo-dopa and carbidopa.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by a neurologist.
- Failure of carbidopa/levo depo, entacapone, ropinirole, pramipexole, selegiline and amantadine.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tazorac (tazarotene)-Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Tazorac is a topical retinoid indicated to treat Acne or Psoriasis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- For Psoriasis patient must have failed medium to high potency topical corticosteroid.
- For acne patient must have failed adapalene or tretinoin or oral tetracycline class antibiotic.
- Must be written by dermatology.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tecentrig (atezolizumab) J9022**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tecentrig is a PDL-1 antagonist used for second line treatment of metastatic bladder cancer and non small cell lung.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Generic Tekturna (aliskiren) STEP THERAPY- DRUG NOT PRIOR AUTHORIZATION**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy	<b>X</b>	Limited Distribution	
		Quantity Limit	

- Tekturna is a step therapy medication indicated to treat hypertension.

Criteria for coverage as follows:

- Tekturna is covered after failure of an Angiotensin Receptor Blocker (ARB).

**Tepezza (teprotumumab)**

Exchange Pharmacy	<b>x</b>	Medical Commercial	<b>X</b>
Commercial Pharmacy	<b>X</b>	Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tepezza is a medication indicated for Thyroid Eye Disease (TED).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Coverage will be provided for 6 months (max total of 8 infusions) and may not be renewed.
- Patient is at least 18 years old; AND
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery or neuro-ophthalmology; AND
- Patient is euthyroid [Note: mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo- or hyperthyroidism promptly)]; AND
- Patient does not have corneal decompensation that is unresponsive to medical management; AND
- Member has not had a decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement)
- Patient does not have poorly controlled diabetes OR inflammatory bowel disease; AND
- Must be used as single agent therapy; AND
- Patient has a clinical diagnosis of active TED that is related to Graves’ Disease (i.e., Graves’ orbitopathy); AND
- Patient has a baseline clinical activity score (CAS) of at least 4; AND
- Patient has active phase TED that is non-sight threatening but has a significant impact on daily living by one or more of the following features- lid retraction  $\geq$  2 mm, OR moderate or severe soft tissue involvement, OR exophthalmos  $\geq$  3 mm above normal for race and gender, OR inconstant or constant diplopia; AND
- Patient’s onset of TED symptoms occurred within the previous 9 months ; AND
- Patient had an inadequate response or intolerance, to high-dose intravenous glucocorticoids OR Rituxumab AND
- Patient is a non-smoker or has recently stopped smoking for at least 6 months.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tetrabenazine (generic xenazine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Xenazine is indicated to treat chorea associated with Huntington’s disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient must have moderate to severe chorea that is refractory to amantadine, neuroleptics or anticonvulsants.
- Prescriber must be a neurologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Thalomid (Thalidomide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written by Oncology, Infectious Disease or in HIV through referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Thyrogen (Thyrotropin alpha)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written by Oncology or Endocrinology.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tracleer (bosentan)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Tracleer is indicated for the treatment of Primary pulmonary arterial hypertension or pulmonary hypertension related to connective tissue disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Pulmonary hypertension must be diagnosed by heart catheterization.
- Patient must have failed or have contraindication to sildenafil, ambrisentan, and tadalafil.
- Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- Approved referrals will initially provide coverage for 12 weeks. Continuation of coverage will be determined by an improvement of an objective test of exercise (6 minute walk) from baseline. Follow-up documentation must be submitted for continuation of coverage.
- Patients who have had an initial positive response based the 12 week follow-up will be approved for an additional 6 months, and re-evaluation with documentation will be required every 6 months for continuation of coverage.
- This medication is contraindicated in pregnancy, those of childbearing ability who are not using contraception, those on glyburide or cyclosporine and in those with active liver disease.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tramadol ER**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tramadol ER is an opioid analgesic
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved after failure of tramadol IR.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Trelegy Ellipta (umeclidinium/fluticasone/vilanterol) - STEP THERAPY DRUG**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy	<b>X</b>	Limited Distribution	
		Quantity Limit	

- Trelegy is used for treatment of moderate to severe COPD and Asthma

Criteria for coverage as follows:

- Covered after failure of a LAMA or LABA containing agent in the past 180 days.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tretinoin (Generic Retin A)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tretinoin is indicated to treat moderate to severe acne and diseases of keratinization such as ichthyosis and keratosis follicularis.
- Prior authorization only required for patients greater than 30 years of age.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- This medication is not covered for wrinkles or photo aging.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tretinoin capsules (generic Vesanoïd)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Vesanoïd is indicated to treat promyelocytic leukemia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Approved when written by Oncology through referrals.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Trintellix (vortioxetine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Trintellix is an antidepressant used to treat major depressive disorder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failure or intolerance to two generically available anti-depressants in past 6 months.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Trisenox (arsenic trioxide) J9017**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Trisenox is indicated to treat acute promyelocytic leukemia (APL).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history, response to previous treatments, and the consideration of other therapeutic options.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tykerb (lapatinib) -Generic**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Tykerb is indicated to treat Advanced HER2+ breast cancer in combination with Xeloda.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Patient has HER2/neu + breast cancer that has failed treatment/progressed with a regimen including an anthracycline, a taxane and Herceptin.
- Used to treat Metastatic HR+ HER2/neu+ breast cancer in combination with an aromatase inhibitor.
- Prescriber is an oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tymlos (abaloparatide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tymlos is indicated to treat osteoporosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Patient is diagnosed with osteoporosis with a BMD less than -2.5.
- Patient fails treatment with IV bisphosphonate and denosumab.
- Exclusions – children, adolescents, Paget’s patients with Paget’s disease or hypercalcemia, or patients with a history of primary or metastatic bone cancer.
- Limitations of treatment – 2 years of treatment.
- For Patients with Calculated GFR or CRCl < 60ml/min Referral must include recent iPTH
- Vitamin D (25 OH, 1,25 OH) labs. Must be within normal limits.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tysabri (natalizumab) J2323**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tysabri a monoclonal antibody indicated to treat refractory relapsed remitting multiple sclerosis and refractory Crohn’s disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications Prescriber is a neurologist/gastroenterologist.
- Failure of a TNF-antagonist for Crohn’s disease.
- Failure of a first line DMT for multiple sclerosis



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Tyzeka (Telbivudine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Tyzeka is indicated for chronic hepatitis B infection.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Vectibix (Panitumumab) J9303**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

Vectibix is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Velcade (bortezomib) J9044**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Bortezomib is indicated to treat multiple myeloma, and mantle cell lymphoma.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Velphoro (sucroferric oxyhydroxide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Velphoro is a non-calcium based phosphate binder indicated to manage hyperphosphatemia in ESRD.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Patient has ESRD.
- Patient has ecalcium on phosphate binders, or not a candidate for calcium based phosphate binders based on KDOQI guidelines.
- Prescribed by a nephrologist
- Not covered in combination with other non-calcium based phosphate binders

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Venclexta (venetoclax)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Venclexta is a BCL-2 inhibitor indicated for treatment B-cell Lymphomas.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Restricted to Hematology/Oncology.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Ventavis (iloprost) nebulized**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Ventavis is a nebulized prostacyclin analog indicated to treat primary pulmonary arterial hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by a pulmonologist or cardiologist.
- Pulmonary hypertension must be diagnosed by heart catheterization, Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- Patient must be a WHO class III or IV and fail ambrisentan and tadalafil.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Victoza (liraglutide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy	<b>X</b>	Limited Distribution	
		Quantity Limit	

- Victoza is a medication indicated for treatment of type 2 diabetes mellitus.

Criteria for coverage as follows:

- Covered after failure of metformin AND Bydureon

**Covered for use in established cardiovascular disease for patients on a Statin who have failed metformin**

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Visudyne (Verteporfin)**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- This medication is a photo-chemotherapy agent for age related wet macular degeneration.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Voriconazole (generic Vfend)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Voriconazole is an antifungal medication used to treat aspergillosis and other invasive fungal infections.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Two of the following medications have been tried, unless resistance or contraindication precludes use, Itraconazole, fluconazole, ketoconazole.
- Exclusions to pre-requisite medications are Invasive pulmonary aspergillosis, *Scedosporium apiospermum*, and *fusarium*.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Votrient (Pazopanib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- **Votrient is an oral tyrosine kinase inhibitor indicated to treat Renal cell carcinoma, and soft tissue sarcoma.**
- **Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.**

Criteria for coverage as follows:

- **Prescribing restricted to oncology.**

**White blood cell colony stimulating factors Granix/Leukine/Zarzio/Nivastym (filgrastim-aafi),**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

**Zarzio-Filgrastim-sndz, Fulphila, Udenyca, Ziextenzo Leukine- sargramostim)**

**Primary Prophylaxis of febrile neutropenia**

(Any agent listed)

**Consideration should be given to equally effective and safe alternative chemotherapy treatment options that do not require colony stimulating factor (CSF) support, when available.**

One white blood cell (WBC) growth factor agent is considered clinically appropriate for primary prophylaxis of chemotherapy-induced febrile neutropenia when **ALL** of the following (1, 2, and 3) are met:

1. The individual has a **non-myeloid malignancy** and is **NOT receiving concurrent chemotherapy and radiation**;
2. Chemotherapy intent must include one of the following:
  - a. Curative intent (adjuvant treatment for early stage disease, for example),
  - b. Intent is survival prolongation, and **the use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal**
  - c. Intent is symptom management, and **the use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal**
3. The individual falls into one of the following risk categories for FN
  - a. High risk of febrile neutropenia (**≥20%**) based on chemotherapy regimen, OR
  - b. Intermediate risk of FN (**≥10% but <20%**) based on chemotherapy regimen, and **at least ONE** of the following significant risk factors:
    - i. Age > 65,
    - ii. Poor performance status (ECOG 3 or 4, but chemotherapy still indicated),
    - iii. Preexisting neutropenia, for example resulting from bone marrow damage or tumor infiltration (ANC <1500mm<sup>3</sup>),
    - iv. Previous febrile neutropenia episode,
    - v. Liver dysfunction, with bilirubin ≥1.0 or liver enzymes ≥ 2x upper limit of normal,
    - vi. Presence of open wounds or active infections, when chemotherapy cannot be delayed to accommodate recovery,
    - vii. Poor nutritional status (baseline albumin less ≤ 3.5 g/dL or BMI less than 20),

## **Medications Requiring Prior Authorizations**

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

- viii. HIV infection (active),
- ix. Advanced cancer,
- x. Multiple comorbid conditions.

### **Secondary Prophylaxis of febrile neutropenia**

(Any agent listed)

**Secondary prophylaxis** of febrile neutropenia is considered clinically appropriate when there has been a previous neutropenic complication (in the absence of primary prophylaxis), **and a change to the regimen (including dose reduction, schedule change, or change in therapy) would be expected to compromise patient outcome**, particularly in the setting of curative intent.

### **Adjunctive treatment of Febrile Neutropenia (primary prophylaxis not given)**

(Any agent listed)

**Adjunctive treatment** of febrile neutropenia is considered clinically appropriate when **any** of the following risk factors are present:

1. Age > 65
2. Neutrophil recovery is expected to be delayed (greater than 10 days)
3. Neutropenia is profound (less than  $0.1 \times 10^9$ )
4. Active pneumonia
5. Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted)
6. Invasive fungal or opportunistic infection
7. Onset of fever during inpatient stay

*Note: Febrile neutropenia (FN) is defined as an oral temperature > 38.3°C (101.0°F) or 2 consecutive readings of 38.0°C (100.4°F) for 1 hour, with an absolute neutrophil count less than 500 cells/microL ( $0.5 \times 10^9/L$ ) or less than 1000 cells/microL and expected to fall below 500 cells/microL over the next 48 hours.*

### **Other oncologic uses for WBC growth factors**

The following indications by growth factor type are also considered clinically appropriate if the requirements below are met:

#### **Filgrastim/filgrastim-sndz**

1. Acute lymphocytic leukemia (ALL):

## Medications Requiring Prior Authorizations

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

- a. after start of induction or first post-remission chemotherapy course
  - b. as an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
2. Acute myeloid leukemia (AML):
  - a. after induction, re-induction, or consolidation OR
  - b. as an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
3. Aplastic anemia – moderate or severe
4. Hairy cell leukemia – to treat severe neutropenia
5. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment OR
  - c. To mobilize stem cells for collection by pheresis
6. Myelodysplastic syndrome (MDS) –
  - a. to treat recurrent infection OR
  - b. to treat neutrophil count < 500 mm<sup>3</sup>
7. Radiation exposure: following radiation therapy in the absence of chemotherapy, if prolonged delays are expected
8. Radiation exposure: after accidental or intentional body irradiation of doses greater than 2 Gy, (Hematopoietic Syndrome of Acute Radiation Syndrome)
9. Support for dose dense or dose intensive chemotherapy in **at least one of** the following scenarios:
  - a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel
  - b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer
  - c. Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma.

### Peg-filgrastim

1. Acute lymphocytic leukemia (ALL):
  - a. after start of induction or first post-remission chemotherapy course
2. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment
3. Myelodysplastic syndrome (MDS) –
  - a. to treat recurrent infection OR
  - b. to treat neutrophil count < 500 mm<sup>3</sup>
4. Radiation exposure: after accidental or intentional body irradiation of doses greater than 2 Gy, (Hematopoietic Syndrome of Acute Radiation Syndrome)
5. Support for dose dense chemotherapy in the following scenarios:

**Medications Requiring Prior Authorizations**

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

- a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel OR
- b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer OR
- c. Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma.

**Sargramostim**

1. Acute lymphocytic leukemia (ALL):
  - a. after start of induction or first post-remission chemotherapy course
2. Acute myeloid leukemia (AML):
  - a. after induction, re-induction, for individuals over 55 years of age
3. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment OR
  - c. To mobilize stem cells for collection by pheresis
4. Myelodysplastic syndrome (MDS)
  - a. to treat recurrent infection OR
  - b. to treat neutrophil count < 500 mm<sup>3</sup>
5. Radiation exposure: after radiation therapy in the absence of chemotherapy, if prolonged delays are expected
6. Radiation exposure: after accidental or intentional body irradiation of doses greater than 2 Gy, (Hematopoietic Syndrome of Acute Radiation Syndrome)
7. Support for dose dense chemotherapy in the following scenarios:
  - a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel OR
  - b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer OR
  - c. Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma.

**Tbo-filgrastim**

1. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment OR
  - c. To mobilize stem cells for collection by pheresis

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Xalkori (crizotinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

Xalkori is a TKI inhibitor for metastatic NSCLC which is ALK (anaplastic lymphoma kinase) positive, or ROS positive.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Not covered in combination with other tyrosine kinase inhibitors or EGFR inhibitors.
- Must be written by oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Vyvanse (Lisdexamfetamine)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Vyvanse is a stimulant indicated for Binge Eating Disorder or ADHD.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Xartemis (Oxycodone and Acetaminophen) ER Tablets**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Xartemis is an abuse deterrent opioid formulation used for pain.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Medication will be approved through referrals when written by Oncology or pain management.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Xeljanz (tofacitinib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Xeljanz is indicated for treatment of Moderate to severe Rheumatoid arthritis in adults, Psoriatic Arthritis, Ulcerative colitis, JIA
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- For rheumatoid arthritis must be written by Rheumatology, Patient must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS (3 month trial in past 6 months) and a preferred TNF.
- For Psoriatic Arthritis Patient must fail adequate trial of MTX or LEF in past 6 months.
- For ulcerative colitis must be written by a gastroenterologist and had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) and an anti-inflammatory (5-asa, sulfasalazine, balsalazide, mesalamine)

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Xgeva (denosumab) J0897**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Xgeva is a RANKL ligand antagonist indicated to treat osteolytic cancers.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber must be an oncologist or endocrinologist.
- Must have failed or a contraindication to an intravenous bisphosphonate.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Xolair (omalizumab) J2357**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Xolair is an anti-IgE monoclonal antibody indicated for patients 12 years and older with moderate to severe persistent asthma who have a positive skin test or in-vitro reactivity to an aeroallergen and chronic idiopathic urticaria. Xolair was not studied in patients who smoke.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.
- Nasal Polyp indication is covered only by exception and will be based on all available treatment options including nebulized sinus treatments and devices

The following criteria must be met for coverage for severe asthma:

- Prescriber must be a pulmonologist or allergist.
- Patient must have baseline IGE levels within indicated range for Xolair labeling.
- Patient must test positive to an aeroallergen (either skin test or blood test).
- Patient must fail 3 months of therapy on maximal indicated doses of Trelegy.
- Patient must have failed leukotriene receptor antagonist
- Failed Nucala if eosophilic asthma.

The following criteria must be met for coverage for chronic idiopathic urticaria:

- Prescribed by an allergist, immunologist, or dermatologist
- Patient must have a diagnosis of chronic idiopathic urticaria (at least a 6 week history)
- Patient must have tried, for a minimum of 2 weeks and failed 2 of the following antihistamines at maximal doses used to treat CIU: cetirizine(40mg/day), levocetirizine (20mg/day), desloratadine(20mg/day), fexofenadine (540mg/day), loratadine (40mg/day) AND MONTELUKAST

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Xtandi (enzalutamide)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Xtandi is an androgen receptor blocker used for Castrate Resistant Prostate Cancer pre- and post-chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Covered for 6 months and continuation based on lack of disease progression.
- Coverage will be based on failure of Abiraterone for overlapping indications (Metastatic Prostate Cancer and Castrate sensitive high risk non-metastatic cancer).
- Must be prescribed by oncologist or urologist.

**Medications Requiring Prior Authorizations**

Effective Date: 11/1/23

FHCP: MCG004

Review/Revision: 72

**Xyrem (Sodium Oxybate) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- This medication is used for treatment of narcolepsy with cataplexy or excessive daytime sleepiness due to narcolepsy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- Only covered for Narcolepsy with cataplexy.
- Coverage will be based on recent failure of:
  1. Modafinil AND Armodafinil AND Amphetamine/Dextroamphetamine And soriamfetol.
  2. Tricyclic Antidepressant shown to be effective in cataplexy(Clomipramine/Protriptyline) and Venlafaxine (for cataplexy)
  3. Three month discontinuation trials for moderate to highly sedating medications such as benzodiazepines, opioids, anticholinergics, muscle relaxers, atypical antipsychotics, dopamine agonists.
  4. Must be prescribed by physician board certified in sleep medicine.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Yervoy (ipilimumab) J9228**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Yervoy is an immunotherapy used for treatment of cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Not covered in combinations unsupported by the NCCN evidence 2a or greater (i.e. Vemurafenib).
- Doses exceeding 3 mg/kg will only be approved in adjuvant treatment setting.
- Must be prescribed by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zaltrap (ziv-aflibercept) J9400**

Exchange Pharmacy		Medical Commercial	<b>X</b>
Commercial Pharmacy		Medical Exchange	<b>X</b>
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zaltrap is a VEGF antagonist indicated for metastatic colorectal cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Coverage will be based on failure or intolerance of Avastin.
- Must be prescribed by an oncologist/hematologist.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zavesca (miglustat) Generic Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zavesca is indicated for treatment of non-neuropathic Gaucher’s disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zejula (niraparib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zejula is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zelboraf (vemurafenib)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Zelboraf is a BRAF inhibitor indicated to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma, NSCLC, and Metastatic colorectal cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Patient must have BRAF V600E/K mutation.
- Must be written by an oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zolinza (Vorinostat)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zolinza is indicated for cutaneous manifestations of cutaneous T-cell Lymphoma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Failed minimum of two systemic treatments, one of which must be Targretin, unless contraindicated.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zortress (everolimus) capsules**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zortress is an immunosuppressive anti-rejection agent for solid organ transplant.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Prescriber must be a transplant specialist.
- Patient must have failure or intolerance to a calcineurin inhibitor.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zydelig (idelalisib) Tablets**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Zydelig is a PI3K kinase inhibitor for treatment of relapsed Chronic lymphocytic leukemia, relapsed follicular lymphoma, and small lymphocytic lymphoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by oncologist.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zyflo (zileuton)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	<b>X</b>

- Zyflo is indicates for treatment of asthma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Must be written by a pulmonologist.
- Uncontrolled Asthma while on maximal doses of long acting bronchodilators and inhaled corticosteroids AND montelukast.
- 6 months of medication compliance with maintenance treatments.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zykadia (ceritinib) capsules**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Zykadia is a TKI inhibitor indicated for metastatic NSCLC which is ALK (anaplastic lymphoma kinase) positive, it is indicated for patients who have failed/progressed on crizotinib (Xalkori)
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications
- Not covered in combination with other tyrosine kinase inhibitors or EGRf inhibitors.
- Must be written by oncologist.
- Must have progressed on Xalkori.



**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zyprexa Relprevv (Olanzapine injection)**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Zyprexa Relprevv is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- FDA approved indications
- Failure of oral aripiprazole and olanzapine
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.

**Medications Requiring Prior Authorizations**

**Effective Date: 11/1/23**

**FHCP: MCG004**

**Review/Revision: 72**

**Zytiga (Abiraterone) GENERIC Only**

Exchange Pharmacy	<b>X</b>	Medical Commercial	
Commercial Pharmacy	<b>X</b>	Medical Exchange	
Step Therapy		Limited Distribution	<b>X</b>
		Quantity Limit	

- Abiraterone is indicated to treat metastatic prostate cancer. It is taken orally along with prednisone daily.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- FDA approved indications

## **Discrimination is Against the Law**

Florida Health Care Plans complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Florida Health Care Plans does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Florida Health Care Plans:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified Interpreters
  - Information written in other languages

If you need these services, contact Daria Siciliano, RN-BC, CCM.

If you believe that Florida Health Care Plans has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Daria Siciliano, RN-BC, CCM,  
Manager of Member Services,  
1340 Ridgewood Avenue,  
Holly Hill, FL 3211.  
Phone: 1-844-219-6137,  
TTY: TRS Relay 711,  
Fax: 386-676-7149,  
Email: [rights@fhcp.com](mailto:rights@fhcp.com).

You can file grievance in person or by mail, fax, or email. If you need help filing a grievance, Daria Siciliano, RN-BC, CCM Manager of Member Services is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

**FHCP: MCG004**

**Review/Revision: 72**

If you or someone you're helping has questions about **Florida Health Care Plans**, you have the right to get help and information in your language at no cost. To talk to an interpreter, call **1-877-615-4022. (TTY: TRS Relay 711)**

Si usted o alguien a quien ayuda tienen preguntas sobre **Florida Health Care Plans**, tienen derecho a obtener ayuda e información en su idioma de manera gratuita. Para hablar con un intérprete, llame al **1-877-615-4022. (TTY: TRS Relay 711)**

Si ou menm, oswa yon moun w ap ede, gen kesyon sou **Florida Health Care Plans**, ou gen dwa pou jwenn enfòmasyon nan lang ou gratis. Pou ale ak yon entèprèt, rele **1-877-615-4022. (TTY: TRS Relay 711)**

Nếu quý vị, hoặc người nào đó mà quý vị đang giúp đỡ, có các thắc mắc về **Florida Health Care Plans**, quý vị có quyền được nhận trợ giúp và thông tin bằng ngôn ngữ của quý vị miễn phí. Để trao đổi với phiên dịch, hãy gọi theo số **1-877-615-4022. (TTY: TRS Relay 711)**

Se você, ou alguém que estiver a ajudar, tiver dúvidas sobre **Florida Health Care Plans**, tem o direito de obter ajuda e informações na sua língua, sem nenhuma custas. Para falar com um intérprete, ligue para **1-877-615-4022. (TTY: TRS Relay 711)**

如果您或您正協助的某人對**Florida Health Care Plans**有疑問，您有權免費以您的語言取得本協助及資訊。如欲與口譯員交談，請致電**1-877-615-4022. (TTY: TRS Relay 711)**

Si vous ou une personne que vous aidez avez des questions au sujet de **Florida Health Care Plans**, vous avez le droit d'obtenir gratuitement de l'aide et des informations dans votre langue. Pour parler à un interprète, veuillez appeler le **1-877-615-4022. (TTY: TRS Relay 711)**

Kung ikaw, o ang isang taong tinutulungan mo, ay may mga tanong tungkol sa **Florida Health Care Plans**, mayroon kang karapatang humingi ng tulong at impormasyon sa iyong wika nang walang bayad. Upang makipag-usap sa isang interpreter, tumawag sa **1-877-615-4022. (TTY: TRS Relay 711)**

Если у Вас или у кого-то, кому Вы помогаете, есть вопросы о программе **Florida Health Care Plans**, Вы имеет право бесплатно получить ответы в переводе на Ваш язык. Для того чтобы воспользоваться помощью устного переводчика, позвоните по телефону **1-877-615-4022. (TTY: TRS Relay 711)**

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**FHCP: MCG004**

**Review/Revision: 72**

**se voi, o una persona che state aiutando, avete domande relative al Florida Health Care 33Plans, avete diritto a ottenere assistenza e informazioni gratuitamente nella vostra lingua. Per parlare con un interprete, chiamare il numero 1-877-615-4022. (TTY: TRS Relay 711)**

**Falls Sie oder jemand, dem Sie helfen, irgendwelche Fragen über Florida Health Care Plans haben, so haben Sie Anspruch auf kostenlose Unterstützung und Informationen in Ihrer eigenen Sprache. Bitte rufen Sie uns unter der Nummer 1-877-615-4022. (TTY: TRS Relay 711) an, um mit einem Dolmetscher/einer Dolmetscherin zu sprechen.**

**귀하 또는 귀하가 도와드리고 있는 분이 Florida Health Care Plans에 관한 질문이 있을 경우, 귀하에게는 무료로 본인이 구사하는 언어로 도움과 정보를 받을 권리가 있습니다. 통역으로 전화 연결되려면 1-877-615-4022. (TTY: TRS Relay 711) 번으로 전화해 주십시오.**

**Jeśli Ty lub ktoś, komu pomagasz macie pytania dotyczące Florida Health Care Plans, macie prawo uzyskać pomoc i informacje w swoim języku, bez żadnych kosztów. Porozmawiaj z tłumaczem, zadzwoń pod numer 1-877-615-4022. (TTY: TRS Relay 711)**

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**หากคุณ หรือคนที่คุณกำลังช่วยเหลืออยู่มีคำถามเกี่ยวกับ Florida Health Care Plans คุณจะได้รับการช่วยเหลือและได้รับข้อมูลในภาษาของคุณโดยที่ไม่มีค่าใช้จ่ายใดๆ หากต้องการพูดคุยกับล่ามแปลภาษา โทร. 1-877-615-4022. (TTY: TRS Relay 711)**