Title: Q1 2019 PDL Changes

The following list of recommended Preferred Drug List (PDL) changes were reviewed and approved by the MHS Pharmacy & Therapeutics (P&T) Committee on January 16th, 2019.

Table 1: Summary PDL Changes – Effective 3/1/2019

Drug	Action	Notes:
Galafold (Migalastat HCl)	Add to PDL with PA	A. Fabry Disease (must meet all): 1. Diagnosis of Fabry disease; 2. Prescribed by or in consultation with a clinical geneticist; 3. Age ≥ 18 years; 4. Presence of at least one amenable GLA variant (mutation), as confirmed by one of the following resources (a, b, or c): a. Galafold Prescribing Information brochure (package insert; Section 12, Table 2); b. Amicus Fabry GLA Gene Variant Search Tool:; c. Amicus Medical Information 5. Galafold is not prescribed concurrently with Fabrazyme; 6. Dose does not exceed 123 mg (1 capsule) every other day.
Delstrigo (Doravirine-Lamivudine-Tenofovir DF)	Add to PDL with ST	Trial of Symfi for treatment naïve members.

New Drug Specific PA Criteria: Full Medical Necessity Crieria Posted at:
https://www.mhsindiana.com/providers/resources/clinical-payment-policies.html

Clinical Policy: Amikacin (Arikayce)
Reference Number: CP.PHAR.401

Initial Approval Criteria
A. Mycobacterium Avium Complex (MAC) (must meet all)**:**
1. Diagnosis of MAC;
2. Prescribed by or in consultation with an infectious disease specialist or pulmonologist;
3. Age ≥ 18 years;
4. Failure, as evidenced by positive sputum culture, of at least a 6-month trial of a multidrug background regimen therapy at up to maximally indicated doses *(see Appendix B)*, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one vial

Clinical Policy: Emapalumab-lzsg (Gamifant)
Reference Number: CP.PHAR.402

Initial Approval Criteria
A. Primary Hemophagocytic Lymphohistiocytosis (must meet all)**:**
1. Diagnosis of primary HLH (i.e., familial (inherited) HLH);

2. Prescribed by or in consultation with a hematologist;
3. Failure of conventional HLH therapy that includes an etoposide- and dexamethasonebased regimen, unless contraindicated or clinically significant adverse effects are experienced;
4. Documentation of a scheduled bone marrow or hematopoietic stem cell transplantation (HSCT) or identification of a transplant donor is in process;
5. Dose does not exceed 10 mg/kg per dose, two doses per week.
Approval duration: 2 months

Clinical Policy: Fremanezumab-vfrm (Ajovy)

Reference Number: CP.PHAR.403

I. Initial Approval Criteria
A. Migraine Prophylaxis (must meet all)**:**
1. Diagnosis of episodic or chronic migraine;
2. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Age ≥ 18 years;
5. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
6. Member has not received Botox® within the previous 12 weeks;
7. Dose does not exceed one of the following (a or b):
a. 225 mg (1 injection) once monthly;
b. 675 mg (3 injections) every 3 months.
Approval duration: 3 months

Clinical Policy: Galcanezumab-gnlm (Emgality)
Reference Number: CP.PHAR.404

I. Initial Approval Criteria
A. Migraine Prophylaxis (must meet all)**:**
1. Diagnosis of episodic or chronic migraine;
2. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Age ≥ 18 years;
5. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
6. Member has not received Botox® within the previous 12 weeks;
7. Dose does not exceed:
a. Loading dose: 240 mg (2 injections) once;
b. Maintenance dose: 120 mg

Clinical Policy: Inotersen (Tegsedi)
Reference Number: CP.PHAR.405

I. Initial Approval Criteria
A. Hereditary Transthyretin-Mediated Amyloidosis (must meet all)**:**
1. Diagnosis of hATTR with polyneuropathy;
2. Documentation confirms presence of a transthyretin (TTR) mutation;
3. Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy;
4. Prescribed by or in consultation with a neurologist;
5. Age ≥ 18 years;
6. Member has not had a liver transplant;
7. Dose does not exceed 284 mg (1 syringe) per week.
Approval duration:
Medicaid/HIM – 6 months

Clinical Policy: Lorlatinib (Lorbrena)
Reference Number: CP.PHAR.406

I. Initial Approval Criteria
A. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is characterized by both of the following (a and b):
a. Recurrent, advanced or metastatic;
b. ALK or ROS1 positive;
5. If disease is ALK-positive, failure of alectinib (Alecensa®), brigatinib (Alunbrig®), or ceritinib (Zykadia®) unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Alecensa, Alunbrig, and Zykadia*

6. If disease is ROS1-positive, failure of crizotinib (Xalkori®) or ceritinib (Zykadia) unless contraindicated or clinically significant adverse effects are experienced [offlabel];
**Prior authorization may be required for Xalkori and Zykadia*
7. Request meets one of the following (a or b):
a. Dose does not exceed 100 mg per day;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
Approval duration:
Medicaid/HIM – 6 months

Clinical Policy: Lusutrombopag (Mulpleta)
Reference Number: CP.PHAR.407

I. Initial Approval Criteria
A. Thrombocytopenia (must meet all)**:**
1. Diagnosis of chronic liver disease;
2. Prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist;
3. Age ≥ 18 years;
4. Recent (within the past 14 days) platelet count is < 50 x 109/L;
5. Member is scheduled to undergo a medical or dental procedure within the next 30 days;
6. Dose does not exceed 3 mg per day (1 tablet per day).
Approval duration: 14 days (no more than 7 total days of treatment)

Clinical Policy: Niraparib (Zejula)
Reference Number: CP.PHAR.408

I. Initial Approval Criteria
A. Ovarian Cancer (must meet all)**:**
1. Diagnosis of epithelial ovarian cancer including fallopian tube or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Completed ≥ 2 platinum-based chemotherapy regimens and is in a complete or partial response;
5. Request meets one of the following (a or b):
a. Dose does not exceed 300 mg (3 capsules) per day;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
Approval duration:
Medicaid – 6 months

Clinical Policy: Talazoparib (Talzenna)
Reference Number: CP.PHAR.409

I. Initial Approval Criteria
A. Breast Cancer (must meet all)**:**

1. Diagnosis of metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease;
5. Mutations in the BRCA genes as detected by an FDA-approved test (e.g., BRACAnalysis CDx);
6. Dose does not exceed 1 mg (1 capsule) per day.

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

Clinical Policy: Cenegermin-bkbj (Oxervate)

Reference Number: CP.PMN.186

I. Initial Approval Criteria
A. Neurotrophic Keratitis (must meet all)**:**
1. Diagnosis of neurotrophic keratitis;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 2 years;
4. Dose does not exceed 1 vial per affected eye per day.

Approval duration: 8 weeks

Clinical Policy: Icosapent ethyl (Vascepa)

Reference Number: CP.PMN.187

I. Initial Approval Criteria
A. Hypertriglyceridemia (must meet all)**:**
1. Diagnosis of hypertriglyceridemia;
2. Age ≥ 18 years;
3. Fasting triglycerides ≥ 500 mg/dL (lab must be dated within 90 days);
4. Failure of a ≥ 3 consecutive month trial of fibrate therapy in the last 6 months at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of omega-3-acid ethyl esters (generic Lovaza®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 4 g (4 capsules) per day.

Approval duration: 6 months

Clinical Policy: Omadacycline (Nuzyra)

Reference Number: CP.PMN.188

I. Initial Approval Criteria
A. Acute Bacterial Skin and Skin Structure Infections, Community-Acquired Bacterial Pneumonia (must meet all)**:**
1. Diagnosis of ABSSSI or CABP;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b):

a. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
b. Both of the following (i and ii):
i. Culture and sensitivity (C&S) report for the current infection shows isolated pathogen is an organism susceptible to omadacycline, unless provider submits documentation that obtaining a C&S report is not feasible;
ii. Member meets one of the following (a, b, or c):
a) Failure of ≥ 2 formulary antibiotics to which the isolated pathogen is susceptible (if available) per C&S report, unless all are contraindicated or clinically significant adverse effects are experienced;
b) C&S report shows resistance or lack of susceptibility of the isolated pathogen to all formulary antibiotics FDA-approved for member's diagnosis;
c) If provider documents that obtaining a C&S report is not feasible: Failure of ≥ 2 formulary antibiotics indicated for member's diagnosis (if available), unless all are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed one of the following (a or b):
a. ABSSSI:
i. Loading dose: 200 mg IV (2 vials) on Day 1;
ii. Maintenance dose: 100 mg IV (1 vial) per day or 300 mg PO (2 tablets) per day;
b. CABP:
i. Loading dose: 200 mg IV (2 vials) on Day 1 or 450 mg PO (3 tablets) per day on Days 1 and 2;
ii. Maintenance dose: 100 mg IV (1 vial) per day or 300 mg PO (2 tablets) per day.
Approval duration: Duration of request or up to 14 days of total treatment, whichever is less

Clinical Policy: Sarecycline (Seysara)
Reference Number: CP.PMN.189

I. Initial Approval Criteria
A. Acne Vulgaris (must meet all)**:**
1. Diagnosis of acne vulgaris;
2. Age ≥ 9 years;
3. Failure of two preferred oral tetracycline antibiotics (e.g., immediate-release minocycline, doxycycline), each used for 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 150 mg (1 tablet) per day.
Approval duration: 12 weeks

Clinical Policy: Segesterone acetate/Ethinyl estradiol (Annovera)
Reference Number: CP.PMN.190

I. Initial Approval Criteria
A. Contraception (must meet all)**:**
1. Prescribed for prevention of pregnancy;
2. Failure of two formulary contraceptive alternatives, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 1 vaginal system per year.
Approval duration: 12 months