Title: Q3 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 July 17, 2019.

Table 1: Summary PDL Additions: Effective 9/1/2019

Drug	Action	Notes:
Nivestym (Filgrastim-aafi)	Move to preferred	PA required

Table 2: New Drug Specific PA Criteria: Full Medical Necessity Criteria Attached and also Posted at: https://www.mhsindiana.com/providers/resources/clinical-payment-policies.html

Drug: Mavenclad	**Criteria: Initial Approval Criteria** **A. Multiple Sclerosis** (must meet all)**:** 1. Diagnosis of one of the following (a or b): a. Relapsing-remitting MS (RRMS), and failure of one of the following (i or ii) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: i. Tecfidera® or Gilenya™ and any of the following: an interferon-beta agent *(Avonex® and Plegridy® are preferred)* or glatiramer *(generic [including Glatopa®] is preferred)*; ii. Tecfidera and Gilenya; b. Secondary progressive MS (SPMS); 2. Prescribed by or in consultation with a neurologist; 3. Age 18 years and older 4. Mavenclad is not prescribed concurrently with other disease modifying therapies for MS 5. Dose does not exceed any of the following: 2 tablets per day, 10 tablets per cycle, 2 cycles per course, 1 course per year. **Approval duration: 12 months - up to 1 course *(2 courses lifetime total)***
Drug: Erdafitinib (Balversa)	**Criteria: Initial Approval Criteria** **A. Urothelial Carcinoma** (must meet all)**:** 1. Diagnosis of locally advanced or metastatic urothelial carcinoma; 2. Prescribed by or in consultation with an oncologist; 3. Age 18 years and older 4. Presence of susceptible FGFR3 or FGFR2 genetic alterations 5. Disease has progressed during or following at least one line of platinum-containing chemotherapy; 6. Request meets one of the following (a or b):

	a. Dose does not exceed 9 mg (3 tablets) 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:**– 6 months
Drug: Risankizumab-rzaa (Skyrizi)	**Initial Approval Criteria** **A. Plaque Psoriasis** (must meet all)**:** 1. Diagnosis of PsO; 2. Prescribed by or in consultation with a dermatologist or rheumatologist; 3. Age 18 years and older 4. Member meets one of the following (a or b): a. Failure of a 3 consecutive month trial of methotrexate up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; b. If intolerance or contraindication to MTX, failure of a 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 5. Failure of a 3 consecutive month trial of adalimumab, unless contraindicated or clinically significant adverse effects are experienced; 6. Dose does not exceed 150 mg at weeks 0 and 4, then every 12 weeks thereafter. **Approval duration: 6 months**
Drug: Romosozumab-aqqg (Evenity™)	**I. Initial Approval Criteria** **A. Osteoporosis** (must meet all)**:** 1. Diagnosis of osteoporosis; 2. Age 18 years or older 3. Member is a postmenopausal female; 4. Member meets one of the following (a or b): a. Prescribed by or in consultation with one of the following specialists: a gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedist, or physiatrist; b. Failure of a 12-month trial of a bisphosphonate *(alendronate is preferred)* at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 5. Dose does not exceed 210 mg (2 prefilled syringes) per month. **Approval duration: 6 months (limited to 12 months cumulative use)**
Drug: Siponimod (Mayzent®)	**Initial Approval Criteria** **A. Multiple Sclerosis** (must meet all)**:** 1. Diagnosis of one of the following (a, b, or c):

	a. Clinically isolated syndrome, and member is contraindicated or has experienced clinically significant adverse effects to an interferon-beta agent *(Avonex® and Plegridy® are preferred)* at up to maximally indicated doses; b. Relapsing-remitting MS, and failure of one of the following (i or ii) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: i. Tecfidera® or Gilenya™ and any of the following: an interferon-beta agent *(Avonex and Plegridy are preferred)* or glatiramer *(generic [including Glatopa®] is preferred)*; ii. Tecfidera and Gilenya; c. Secondary progressive MS; 2. Prescribed by or in consultation with a neurologist; 3. Age 18 or older 4. Documentation that member does not have a CYP2C9*3*3 genotype 5. Mayzent is not prescribed concurrently with other disease modifying therapies for MS 6. Dose does not exceed 2 mg per day. **Approval duration: 6 months**
Drug: Solriamfetol (Sunosi™)	**Initial Approval Criteria** **A. Narcolepsy** (must meet all)**:** 1. Diagnosis of narcolepsy; 2. Prescribed by or in consultation with a neurologist; 3**.** Age 18 years or older 4. Failure of a 1-month trial of one of the following central nervous system stimulants at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: amphetamine immediate-release (IR), amphetamine, dextroamphetamine IR, dextroamphetamine, or methylphenidate IR; 5. Failure of a 1-month trial of armodafinil (Nuvigil®) or modafinil (Provigil®) at up to maximally indicated doses, unless clinically significant side effects are experienced; 6. Dose does not exceed 150 mg per day. **Approval duration:** 12 months **B. Obstructive Sleep Apnea** (must meet all)**:** 1. Diagnosis of OSA; 2. Age 18 years or older 3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy for at least 1 month; 4. Failure of a 1-month trial of armodafinil (Nuvigil®) or modafinil (Provigil®) at up to maximally indicated doses, unless clinically significant side effects are experienced;

	5. Dose does not exceed 150 mg per day. **Approval duration:** 12 months
Drug: Tegaserod maleate (Zelnorm)	**Irritable Bowel Syndrome with Constipation** (must meet all)**:** 1. Diagnosis of IBS-C; 2. Age 18 years or older 3. Failure of one bulk forming laxative (e.g., psyllium [Metamucil®], methylcellulose[Citrucel®], calcium polycarbophil [FiberCon®]), unless contraindicated or clinically significant adverse effects are experienced; 4. Failure of Linzess®, Amitiza®, or Trulance® (whichever is preferred), unless contraindicated or clinically significant adverse effects are experienced; 5. At the time of request, member does not have any of the following contraindications: a history of myocardial infarction, stroke, transient ischemic attack, or angina; 6. Dose does not exceed 12 mg (2 tablets) per day. **Approval duration: 12 months**
Drug: Triclabendazole (Egaten)	**Initial Approval Criteria** **A. Fascioliasis** (must meet all)**:** 1. Diagnosis of fascioliasis; 2. Prescribed by or in consultation with an infectious disease specialist or gastroenterologist; 3. Age: 6 years or older 4. Dose does not exceed 10 mg/kg per dose for 2 doses. **Approval duration: 4 weeks (no more than 2 total doses)**