Title: Q4 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 October 16, 2019.

Table 1: Summary PDL Additions: Effective 12/1/19

Drug	Action	Notes:
Sprivia Respimat 1.25 mcg	Add to PDL	

Summary Policy Additions: Effective 12/16/19

Policy	Notes:
CP.PHAR.65 Imatinib (Gleevec)	PVNS/TGCT: added requirement that disease is not amenable to improvement with surgery to align with Turalio since both drugs have the same recommendations for use per NCCN.
CP.PHAR.79 Lapatinib (Tykerb)	Added bone cancer off-label use criteria per NCCN 2A recommendation; references reviewed and updated.
CP.PHAR.98 Ruxolitinib (Jakafi)	Criteria added for new FDA indication: steroid-refractory acute graft-versus-host disease; references reviewed and updated.
CP.PHAR.129 Venetoclax (Venclexta)	CLL/SLL monotherapy or combination therapy with rituximab added in the subsequent therapy setting; AML NCCN alternative uses for relapse/refractory disease and remission added; Appendix B updated to reconcile with similar policies; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.130 Avatrombopag (Doptelet)	Criteria added for new FDA indication: chronic immune thrombocytopenia; references reviewed and updated.
CP.PHAR.133 Idelalisib (Zydelig)	Criteria/Appendix B reorganized to reconcile with similar policies; FDA/NCCN dosing limitation added, references reviewed and updated.
CP.PHAR.137 Ivosidenib (Tibsovo)	FDA/NCCN dosing limitation added; induction therapy examples for patients over 60 added; references reviewed and updated.

CP.PHAR.138 Lenvatinib (Lenvima)	NCCN designation of recurrent added to MTC criteria; references reviewed and updated.
CP.PHAR.169 Vigabatrin (Sabril)	For Refractory Complex Partial Seizures (CPS): Modified failure of two preferred alternative anticonvulsant drugs to a failure of three agents; references reviewed and updated.
CP.PHAR.171 Goserelin Acetate (Zoladex)	Removed pregnancy safety requirement for breast cancer and endometriosis indications; added oncologist prescriber requirement for breast cancer; for prostate cancer removed requirement for use of 3.6 mg or 10.8 mg strengths as those are the only available strengths, added urologist specialist option; for dysfunctional uterine bleeding added requirement to Section I and II to validate member has not yet received two implants; references reviewed and updated.
CP.PHAR.172 Histrelin Acetate (Vantas, Supprelin LA)	Prostate cancer – removed the following as there is no preferred product among the GnRH agonists and the requirement is not included for the CPP indication which is similarly for an implant formulation: “Documentation showing a history of ≥ 3 months of gonadotropin-releasing hormone (GnRH) agonist injections that were effective and well tolerated”, added urologist specialist option; references reviewed and updated.
CP.PHAR.173 Leuprolide Acetate	Added urologist specialist option; references reviewed and updated.
CP.PHAR.175 Triptorelin pamoate (Trelstar, Triptodur)	For prostate cancer added option for urologist prescribing; references reviewed and updated.
CP.PHAR.231 IncobotulinumtoxinA (Xeomin)	Criteria updated for new FDA approved indication: first-line treatment for blepharospasms; references reviewed and updated.
CP.PHAR.245 Apremilast (Otezla)	Criteria added for new FDA indication: treatment of adult patients with oral ulcers associated with Behçet’s disease; references reviewed and updated.
CP.PHAR.260 Rituximab (Rituxan,	Criteria added for off-label use in neuromyelitis optica spectrum disorder; references reviewed and updated.

Truxima, Rituxan Hycela)	
CP.PHAR.314 Romidepsin (Istodax)	FDA dosing cycle details added; FDA/NCCN labeling requirement added; references reviewed and updated.
CP.PHAR.324 Temsirolimus (Torisel)	Updated NCCN dosing per new template; added RCC prognostic risk factors; references reviewed and updated.
CP.PHAR.336 Dupilumab (Dupixent)	Criteria added for new FDA indication: CRSwNP; added allergists as potential prescribers for atopic dermatitis; references reviewed and updated.
CP.PHAR.363 Enasidenib (Idhifa)	NCCN use added - relapse/remission post Idhifa therapy; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.400 Duvelisib (Copiktra)	FDA/NCCN dosing limitation added; marginal zone lymphomas added per NCCN; references reviewed and updated.
CP.PHAR.404 Galcanezumab-gnlm (Emgality)	Criteria added for new FDA approved indication: episodic cluster headaches; added chronic cluster headaches to Section III as a diagnosis not covered; references reviewed and updated.
CP.PMN.47 Rifaximin (Xifaxan)	For SIBO added requirement for age 18 or older; references reviewed and updated.

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 **Effective 12/16/19**

Drug: **Darolutamide (Nubeqa)**	**I. Initial Approval Criteria** A. **Prostate Cancer** (must meet all)**:** 1. Diagnosis of nmCRPC; 2. Prescribed by or in consultation with an oncologist or urologist; 3. Age ≥ 18 years; 4. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently (*see Appendix D*) or has had a bilateral orchiectomy; 5. Request meets one of the following (a or b):* a. Dose does not exceed 1,200 mg (4 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*).

	**Prescribed regimen must be FDA-approved or recommended by NCCN.*
Drug: **Pexidartinib (Turalio)**	**1. Initial Approval Criteria** a. **Tenosynovial Giant Cell Tumor** (must meet all)**:** 1. Diagnosis of TGCT (also known as giant cell tumor of the tendon sheath [GCT-TS] or pigmented villonodular synovitis [PVNS]); *2.* Prescribed by or in consultation with an oncologist; 3. Age ≥ 18 years; 4. Disease is associated with severe morbidity or functional limitations and is not amenable to improvement with surgery; 5. Request meets one of the following (a or b):* a. Dose does not exceed 800 mg (4 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*). **Prescribed regimen must be FDA-approved or recommended by NCCN*
Drug: **Thioguanine (Tabloid)**	**I. Initial Approval Criteria** A. **Acute Myeloid Leukemia or Acute Lymphoblastic Leukemia** (must meet all)**:** 1. Diagnosis of one of the following (a or b): a. Acute myeloid leukemia (AML); b. Acute lymphoblastic leukemia (ALL) and member is < 18 years of age; *2.* Prescribed by or in consultation with an oncologist or hematologist; 3. Request meets one of the following (a or b):* a. Dose does not exceed 200 mg/m^2 per day; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*). **Prescribed regimen must be FDA-approved or recommended by NCCN.*
Drug: **Trientine (Syprine)**	**I. Initial Approval Criteria** **A. Wilson's Disease** (must meet all)**:** 1. Diagnosis of Wilson's disease; 2. Age ≥ 6 years;

	3. Failure of penicillamine (*Depen® is preferred*) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; 4. Dose does not exceed one of the following (a or b): a. Age > 12 years: 2,000 mg per day; b. Age ≤ 12 years: 1,500 mg per day.
Drug: **Valrubicin (Valstar)**	**I. Initial Approval Criteria** A. **Bladder Cancer** (must meet all)**:** 1. Diagnosis of recurrent or persistent CIS of the urinary bladder; *2.* Prescribed by or in consultation with an oncologist; 3. Age ≥ 18 years; 4. Failure of intravesical BCG treatment, unless contraindicated or clinically significant adverse effects are experienced; 5. Request meets one of the following (a or b):* a. Dose does not exceed 800 mg per week; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*). **Prescribed regimen must be FDA-approved or recommended by NCCN*
Drug: **Bedaquiline (Sirturo)**	**I. Initial Approval Criteria** A. **Multi-Drug Resistant Tuberculosis** (must meet all)**:** 1. Diagnosis of MDR-TB; *2.* Prescribed by or in consultation with an infectious disease specialist or a pulmonologist; 3. Age ≥ 12 years; 4. Prescribed in combination with at least 3 other anti-tuberculosis agents (*see Appendix B*); 5. Documented resistance to fluoroquinolones, unless contraindicated or clinically significant adverse effects are experienced; 6. Dose does not exceed 400 mg per day for the first 2 weeks, followed by 200 mg three times per week.
Drug: **Ferric Maltol (Accrufer)**	**II. Initial Approval Criteria** A. **Iron Deficiency** (must meet all)**:** 1. Diagnosis of iron deficiency; 2. Age ≥ 18 years;

	3. Failure of two oral iron products (*must be different salts*), unless contraindicated or clinically significant adverse effects are experienced; 4. Dose does not exceed 60 mg (2 capsules) per day.

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