Title: Q3 2020 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 14, 2020.

Table 1: Summary PDL Additions: Effective 10/01/2020

Drug	Action	Notes:
Ubrelvy	Update	Quanity limit of 10 tabs per month

Summary Policy Additions: Effective 10/01/2020

Policy	Notes:
CP.PHAR.81 Pazopanib (Votrient)	3Q 2020 annual review: For STS subtype GIST Ayvakit added per NCCN guidelines as a possible step through drug; for STS added criteria disease is stage IV, unresectable, advanced, or recurrent with metastases as per NCCN guidelines; for uterine carcinoma added criteria disease is recurrent or metastatic; for thyroid carcinoma added criteria disease is unresectable, advanced or metastatic; if papillary, follicular, or Hurthle cell carcinoma, disease is progressive and/or symptomatic iodine-refractory; off-label ovarian cancer added given 2A NCCN recommendation; references reviewed and updated.
CP.PHAR.89 Peginterferon Alfa-2a,b (Pegasys, PegIntron, Sylatron)	3Q 2020 annual review: added systemic mastocytosis with associated hematologic malignancy, aggressive systemic mastocytosis, osteopenia or osteoporosis with refractory bone pain and/or decreasing bone mineral density on bisphosphonate therapy as per NCCN compendium; specified myelofibrosis as low risk and symptomatic as per NCCN compendium; added specialist involvement for chronic hepatitis B infection; references reviewed and updated.
CP.PHAR.302 Ixazomib (Ninlaro)	3Q 2020 annual review: NCCN recommended uses for MM and Waldenstrom added; references reviewed and updated.
CP.PHAR.303 Brentuximab (Adcetris)	Q3 2020 annual review: per NCCN, breast-implant associated ALCL stage restriction removed, primary mediastinal large B-cell lymphoma added, post-transplant lymphoproliferative disorder limited to monomorphic PTLD (T-cell type) inclusive of primary therapy; references reviewed and updated.

CP.PHAR.322 Pembrolizumab (Keytruda)	3Q 2020 annual review: new FDA approved dosing of 400 mg every 6 weeks added to all labeled adult indications; NSCLC: first-line removed from combination with chemotherapy per NCCN; brain metastasis moved under PD-L1 positive disease per NCCN; SCLC: relapsed disease added per NCCN; cHL: Keytruda as single-agent therapy added per NCCN; HNSCC: first-line therapy requirement removed from combination platinum/FU therapy per NCCN; MSI-H/dMMR tumors: first-line therapy for occult primary tumor and small bowel added per NCCN; HCC: Child-Pugh Class A added per NCCN/pivotal trial with no prior checkpoint inhibitor therapy caveat per NCCN; references reviewed and updated.
CP.PHAR.360 Olaparib (Lynparza)	Criteria added for two newly FDA-approved indications: 1) HRD-positive ovarian cancers in combination with bevacizumab after bevacizumab primary therapy, and 2) HRR-mutated mCRPC.
CP.PHAR.365 Neratinib (Nerlynx)	Added NCCN Compendium supported use in combination with capecitabine for CNS metastases; references reviewed and updated.
CP.PHAR.383 Trifluridine-tipiracil (Lonsurf)	3Q 2020 annual review: added advanced CRC, GC, and GEJ per NCCN guidelines; changed T/F of Herceptin to trastuzuamb allowing usage of biosimilars as supported by NCCN guidelines; updated Appendix B; references reviewed and updated.
CP.PHAR.384 Lutetium Lu 177 dotatate (Lutathera)	3Q 2020 annual review: revised criteria requiring disease progression while on a long-acting somatostatin analog to allow short and long acting somatostatin analogs; updated Appendix B and D; references reviewed and updated.
CP.PHAR.424 Fulvestrant (Faslodex Injection)	3Q2020 annual review: for endometrial carcinoma, added option for us in stage II disease, in combination with sequential external beam radiation therapy; references reviewed and updated.
CP.PHAR.433 Polatuzumab vedotin-piiq (Polivy)	3Q 2020 annual review: added; NCCN off-label uses added for HGBL, follicular and mantle cell lymphomas, post-transplant lymphoproliferative disorder, AIDS-related B-cell lymphoma, histologic transformation of nodal marginal lymphoma to DLBCL;
CP.PHAR.478 Selpercatinib (Retevmo)	Drug is now FDA approved - criteria updated per FDA labeling: For NSCLC, failure of platinum-based chemotherapy and PD-1/PD-L1 therapy removed per FDA; recurrent, advanced or metastatic replaces advanced per FDA and NCCN; dosing added; for thyroid cancer, MTC restricted to mutant-positive rather than also fusion-positive;

	failure of systemic therapy removed per FDA; dosing added; references reviewed and updated.
CP.PHAR.408 Niraparib (Zejula)	Criteria added for expanded FDA-indication as maintenance treatment in advanced ovarian, fallopian tube, or primary peritoneal cancer in patients who are in a complete or partial response to first-line platinum-based chemotherapy; added that Zejula must be used as a single agent or in combination with bevacizumab per NCCN recommendations.
CP.PHAR.130 Avatrombopag (Doptelet)	For chronic immune thrombocytopenia: added requirement that Doptelet is not prescribed concurrently with rituximab or other thrombopoietin receptor agonists for ITP; revised systemic corticosteroid and immune globulin trial to tiered re-direction with immune globulin trial only if corticosteroid cannot be used per ASH 2011 guideline and specialist feedback.
CP.PHAR.179 Romiplostim (Nplate)	For immune thrombocytopenia: added requirement that Nplate is not prescribed concurrently with rituximab or other thrombopoietin receptor agonists for ITP.
CP.PHAR.180 Eltrombopag (Promacta)	For chronic immune thrombocytopenia: added requirement that Promacta is not prescribed concurrently with rituximab or other thrombopoietin receptor agonists for ITP .
CP.PHAR.243 Alemtuzumab (Lemtrada)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; references reviewed and updated.
CP.PHAR.249 Dimethyl fumarate (Tecfidera), diroximel fumarate (Vumerity)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization
CP.PHAR.251 Fingolimod (Gilenya)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.252 Glatiramer (Copaxone, Glatopa)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.255 Interferon beta-1a (Avonex, Rebif)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.256 Interferon beta-1b (Betaseron, Extavia)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;

CP.PHAR.258 Mitoxantrone (Novantrone)	MS: added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; references reviewed and updated.
CP.PHAR.259 Natalizumab (Tysabri)	MS: added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.262 Teriflunomide (Aubagio)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.271 Peginterferon beta-1a (Plegridy)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.335 Ocrelizumab (Ocrevus)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.422 Cladribine (Mavenclad)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; references reviewed and updated.
CP.PHAR.427 Siponimod (Mayzent)	Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.460 Monomethyl fumarate (Bafiertam)	Citeria per FDA labeling; modified CIS re-direction to include glatiramer.; added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization.
CP.PHAR.462 Ozanimod (Zeposia)	Criteria per FDA labeling; modified CIS re-direction to include glatiramer; added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization;
CP.PHAR.103 Immune Globulins	3Q 2020 annual review: for dermatomyositis added a requirement for a prior trial of rituximab; added Indiana as another exception to the Section III exclusion for PANDAS; RT4: added new Hizentra prefilled syringe dosage form; references reviewed and updated.

CP.PHAR.150 Mecasermin (Increlex)	3Q 2020 annual review: open epiphyses added; auxology updated for acquired GH insensitivity to reconcile with somatropin policy; malignancy contraindication added; positive response removed in deference to growth criteria; references reviewed and updated.
CP.PHAR.212 Dornase alfa (Pulmozyme)	Added pulmonologist prescriber requirement; added requirement of therapeutic plan including concomitant use of standard CF therapies as indicated in PI.
CP.PHAR.260 Rituximab (Rituxan, Ruxience, Truxima, Rituxan Hycela)	Added criteria for off-label indication of ITP; for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy.
CP.PHAR.285 Nintedanib (Ofev)	3Q 2020 annual review: criteria added for new FDA indication: chronic fibrosing ILD with a progressive phenotype; references reviewed and updated.
CP.PHAR.379 Etelcalcetide (Parsabiv)	3Q 2020 annual review: added to Section I requirement that member does not have serum calcium less than the lower limit of the normal to align with prescribing information and similar Sensipar criteria requirements; modified HIM-Medical Benefit to HIM line of business; references reviewed and updated.
CP.PHAR.465 Teprotumumab (Tepezza)	Added requirement that member has not had previous surgical intervention for TED consistent with clinical trial exclusion criteria.
CP.PMN.14 SGLT2 inhibitors	Heart Failure (must meet all): 1. Diagnosis of HFrEF of NYHA Class II, III, or IV; 2. Request is for Farxiga; 3. Prescribed by or in consultation with a cardiologist; 4. Age ≥ 18 years; 5. Left ventricular ejection fraction (LVEF) is ≤ 40%; 6. Member does not have a diagnosis of type 1 diabetes mellitus; 7. Member is currently receiving standard HF drug therapy at target doses for ≥ 4 weeks including both of the following (a and b) unless clinically significant adverse effects are experienced or all are contraindicated: a. Angiotensin converting enzyme inhibitor, angiotensin receptor blocker, or Entresto®; b. Beta blocker; 8. Dose does not exceed 10 mg (1 tablet) per day.
CP.PMN.40 Acitretin (Soriatane)	3Q 2020 annual review: added rheumatologist as a prescriber option; references reviewed and updated.
CP.PMN.124 Itraconazole (Sporanox ,Onmel, Tolsura)	Added criteria for Sporotrichosis infection (off-label); added requirement for use of generic itraconazole capsules or oral solution; updated Appendix B; updated dosage and administration; references reviewed and updated.

CP.PMN.163 Sodium zirconium cyclosilicate (Lokelma)	3Q 2020 annual review: clarified redirection to preferred sodium polystyrene sulfonate; added to Section III exclusion for emergency treatment of hyperkalemia to align with prescribing information limitation of use and Veltassa; references reviewed and updated.
CP.PMN.183 GLP-1 receptor agonists	Updated "FDA Approved Indications" section to include Trulicity's new FDA indication: cardiovascular risk reduction in patients with established cardiovascular disease or with multiple cardiovascular risk factors; modified criteria to allow Trulicity or Ozempic in patients with established cardiovascular disease or multiple cardiovascular risk factors if contraindicated to the preferred agent Victoza; added new exenatide contraindication to Appendix C; references reviewed and updated.
CP.PMN.208 Halobetasol-Tazarotene (Duobrii)	3Q 2020 annual review: added rheumatologist as prescriber involvement for plaque psoriasis; 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

CP.PHAR.487 Osilodrostat (Isturisa)*	A. **Initial Approval Criteria** B. Cushing's Disease (must meet all): a. Diagnosis of CD; b. Prescribed by or in consultation with an endocrinologist; c. Age ≥ 18 years; d. Member meets one of the following (1 or 2): 1 Pituitary surgery has not been not curative; 2 Member is not eligible for pituitary surgery; Dose does not exceed 30 mg twice daily
CP.PHAR.488 Apomorphine (Apokyn)	A. **Parkinson's Disease** (must meet all)**:** Diagnosis of advanced Parkinson's disease defined as Stages II to IV of the 5-stage Hoehn and Yahr scale (*see Appendix E*); 1. Prescribed by or in consultation with neurologist; 2. Apokyn is prescribed concurrently with an anti-Parkinson agent (e.g. levodopa/carbidopa, dopamine agonists, ropinirole, catechol-O-methyl transferase (COMT) inhibitors, tolcapone, monoamine oxidase type B (MAO-B) inhibitors or rasagiline); 3. Member is experiencing hypomobility episodes at the end of the dosing interval or is experiencing unpredictable hypomobility ("on/off") episodes;

	4. Dose does not exceed 0.6 mL per injection, 5 injections per day, or 2 mL per day.
CP.PHAR.489 Eptinezumab (Vyepti)*	**Initial Approval Criteria** B. **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. Failure of Aimovig®, unless contraindicated or clinically significant adverse effects are experienced; 7. Vyepti is not prescribed concurrently with Botox® or other injectable CGRP inhibitors (e.g., Aimovig, Ajovy®, Emgality®); Dose does not exceed 100 mg (1 vial) once every 3 months
CP.PHAR.490 Rimegepant (Nurtec ODT)*	**Initial Approval Criteria** C. **Migraine** (must meet all)**:** 1. Diagnosis of migraine headache; 2. Age ≥ 18 years; 3. Failure of at least TWO formulary $5HT_{1B/1D}$-agonist migraine medications* (e.g., sumatriptan, rizatriptan, zolmitriptan) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated; **Prior authorization may be required.* 4. For dose increase requests to quantities > 1 box of 8 ODTs per month, member meets all of the following (a, b, and c): a. Failure of at least TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);

	**Prior authorization may be required.* b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B);* **Prior authorization may be required.* c. Member is being treated by or in consultation with a neurologist or headache/pain specialist; 5. Nurtec ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Ubrelvy®, Aimovig®, Ajovy®, Emgality®); 6. Dose does not exceed 75 mg (1 ODT) per day for 15 days per month.
CP.PHAR.494 Capmatinib (Tabrecta)*	**Initial Approval Criteria** D. **Non-Small Cell Lung Cancer** (must meet all)**:** 1. Diagnosis of advanced or metastatic NSCLC (Stage IIIb or IV); 2. Prescribed by or in consultation with an oncologist; 3. Age ≥ 18 years; 4. Disease is positive for a mutation causing MET exon 14 skipping; 5. Disease is epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) negative; 6. Member does not have symptomatic CNS metastases; 7. Request meets one of the following (a or b):* a. Dose does not exceed 800 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*
CP.PHAR.495 Mitomycin for Pyelocalyceal Solution (Jelmyto)*	**Initial Approval Criteria** E. **Low-Grade Upper Tract Urothelial Cancer** (must meet all)**:** 1. Newly diagnosed or recurrent LG-UTUC above the ureteropelvic junction;

	2. Prescribed by or in consultation with an oncologist or urologist; 3. Age ≥ 18 years; 4. Lesion(s) measure ≤ 15 mm; 5. For the affected kidney(s), member does not have a recent history (with the last year) of carcinoma in situ in the urinary tract, invasive urothelial carcinoma, or high-grade papillary urothelial carcinoma; 6. Request meets one of the following (a or b):* c. Dose does not exceed 60 mg once weekly for 6 instillations per kidney; d. 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*
CP.PHAR.496 Pemigatinib (Pemazyre)*	**Initial Approval Criteria** F. **Cholangiocarcinoma** (must meet all)**:** 1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; 2. Prescribed by or in consultation with an oncologist; 3. Age ≥ 18 years; 4. Documentation of FGFR2 fusion or rearrangement; 5. Member has not previously received a selective FGFR inhibitor (e.g., Stivarga®); 6. Failure of at least one previous systemic cancer therapy, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*); 7. Request meets one of the following (a or b):* e. Dose does not exceed 13.5 mg (1 tablet) per day; f. 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*
CP.PHAR.497 Tucatinib (Tukysa)*	**Initial Approval Criteria** G. **Breast Cancer** (must meet all)**:** 1. Diagnosis of advanced unresectable or metastatic breast cancer; 2. Confirmation of HER2 positive disease; 3. Prescribed by or in consultation with an oncologist;

	4. Age ≥ 18 years; 5. Failure of a treatment regimen containing one of the following in the metastatic setting, unless clinically significant adverse effects are experienced or all are contraindicated: trastuzumab (Herceptin®), Perjeta® (pertuzumab), Kadcyla® (ado-trastuzumab emtansine); 6. Request meets one of the following (a or b):* g. Dose does not exceed 600 mg (4 tablets) per day; h. 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*
CP.PMN.236 Amisulpride (Barhemsys)	**Initial Approval Criteria** **A. Postoperative Nausea and Vomiting** (must meet all)**:** 1. Prescribed for the prevention or treatment of PONV; 2. Member is scheduled to undergo surgery; 3. Member meets one of the following (a or b): a. For prevention: Failure of one generic formulary agent for PONV at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*); b. For treatment: Member did not receive a preoperative D2 antagonist (e.g., metoclopramide); 4. Request meets one of the following (a or b): a. For prevention: Dose does not exceed 5 mg once; For treatment: Dose does not exceed 10 mg once
CP.PMN.237 Bempedoic acid (Nexletol), bempedoic acid-ezetimibe (Nexlizet)*	**II. Initial Approval Criteria** A. **Heterozygous Familial Hypercholesterolemia and Atherosclerotic Cardiovascular Disease** (must meet all)**:** 1. Diagnosis of one of the following (a or b): a. ASCVD as evidenced by a history of any one of the following conditions (i-vii): i. Acute coronary syndromes; ii. Clinically significant coronary heart disease (CHD) diagnosed by invasive or noninvasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging); iii. Coronary or other arterial revascularization; iv. Myocardial infarction; v. Peripheral arterial disease presumed to be of atherosclerotic origin;

	vi. Stable or unstable angina; vii. Stroke or transient ischemic attack (TIA); b. HeFH, and member meets both of the following (i and ii): i. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was ≥ 190 mg/dL; ii. HeFH diagnosis is confirmed by one of the following (a or b): a) World Health Organization (WHO)/Dutch Lipid Network familial hypercholesterolemia diagnostic criteria score of > 8 as determined by requesting provider (*see Appendix D*); b) Definite diagnosis per Simon Broome criteria (*see Appendix D*); 2. Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist; 3. Age ≥ 18 years; 4. For members on statin therapy, both of the following (a and b): a. Nexletol or Nexlizet is prescribed in conjunction with a statin at the maximally tolerated dose; b. Member has been adherent for at least the last 4 months to maximally tolerated doses of one of the following statin regimens (i, ii, or iii): i. A high intensity statin (*see Appendix E*); ii. A moderate intensity statin (*see Appendix E*) and member has one of the following (a or b): a) Intolerance to <u>two</u> high intensity statins; b) A statin risk factor (*see Appendix G*); iii. A low intensity statin and member has one of the following (a or b): a) Intolerance to <u>one</u> high and <u>one</u> moderate intensity statins; b) A statin risk factor (*see Appendix G*) and history of intolerance to <u>two</u> moderate intensity statins; 5. For members not on statin therapy, member meets one of the following (a or b): a. Statin therapy is contraindicated per Appendix F; b. For members who are statin intolerant, member has tried at least <u>two</u> statins, 1 of which must be a hydrophilic statin (pravastatin, fluvastatin, or rosuvastatin), and member meets one of the following (i or ii):

	i. Member has documented statin risk factors (*see Appendix G*); ii. Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b): a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge; b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly); 6. Member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 4 months, unless contraindicated per Appendix F or a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection); 7. For Nexletol, documentation that ezetimibe will be prescribed concurrently for as long as Nexletol is prescribed, unless contraindicated per Appendix F or a history of ezetimibe intolerance exists (e.g., associated diarrhea or upper respiratory tract infection); 8. Documentation of recent (within the last 60 days) LDL-C of one of the following (a or b): a. ≥ 70 mg/dL for ASCVD; b. ≥ 100 mg/dL for HeFH; 9. Treatment plan does not include coadministration with Repatha® or Praluent®; 10. Dose does not exceed either of the following (a or b): a. Nexletol: 180 mg per day; b. Nexlizet: bempedoic acid 180 mg/ezetimibe 10 mg per day.
CP.PMN.238 Carbidopa-Levodopa ER Capsules (Rytary)	**III. Initial Approval Criteria** A. **Parkinson's Disease or Parkinsonism** (must meet all)**:** 1. Diagnosis of PD or parkinsonism; 2. Age ≥ 18 years; 3. Documented intolerance or contraindication* to carbidopa-levodopa sustained release tablets (Sinemet® CR) that would not apply to Rytary; Dose does not exceed carbidopa 612.5 mg/levodopa 2,450 mg per day
CP.PMN.239 Chenodiol (Chenodal)	**Initial Approval Criteria** B. **Radiolucent Gallstones** (must meet all)**:**

	1. Presence of radiolucent stones in well-opacifying gallbladders; 2. Age ≥ 18 years; 3. Failure of a 6-month trial of ursodiol, unless contraindicated or clinically significant adverse effects are experienced; 4. Member is not a candidate for surgery (e.g., due to systemic disease or age); 5. Dose does not exceed 18 mg per kg per day.
CP.PMN.240 Gabapentin ER (Gralise, Horizant)	**IV. Initial Approval Criteria** A. **Postherpetic Neuralgia** (must meet all)**:** 1. Diagnosis of PHN; 2. Age ≥ 18 years; 3. Failure of a ≥ 30 day trial of immediate-release gabapentin at ≥ 1,800 mg per day, unless contraindicated to its excipients or clinically significant adverse effects are experienced; 4. Dose does not exceed (a or b): a. Gralise: 1,800 mg (3 tablets) per day; b. Horizant: 1,200 mg (2 tablets) per day. B. **Restless Leg Syndrome** (must meet all)**:** 1. Diagnosis of RLS; 2. Request is for Horizant; 3. Age ≥ 18 years; 4. Failure of ropinirole and pramipexole at up to maximally indicated doses, each used for ≥ 30 days, unless both are contraindicated or clinically significant adverse effects are experienced; Dose does not exceed 600 mg (1 tablet) per day
CP.PMN.241 Lactitol (Pizensy)*	**V. Initial Approval Criteria** A. **Chronic Idiopathic Constipation** (must meet all)**:** Diagnosis of CIC; 1. Age ≥ 18 years; 2. Failure of one bulk forming laxative (e.g., psyllium [Metamucil®], methylcellulose [Citrucel®], calcium polycarbophil [FiberCon®]), unless all are contraindicated or clinically significant adverse effects are experienced; 3. Failure of polyethylene glycol (MiraLax®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 4. Medical justification why lactulose (Constulose®) cannot be used;

	5. Dose does not exceed 20 gm (2 unit-dose packets) per day or one bottle per month.
CP.PMN.242 Minocycline micronized foam (Amzeeq)	**VI. Initial Approval Criteria** A. **Acne Vulgaris** (must meet all)**:** 1. Diagnosis of acne vulgaris; 2. Age ≥ 9 years; 3. Failure of ≥ 2 of the following topical preparations, each from different medication classes, each used for ≥ 2 months, unless all are contraindicated or clinically significant adverse effects are experienced: a. Topical antibiotics: clindamycin, erythromycin; b. Topical anti-infectives: benzoyl peroxide; c. Topical retinoids: tretinoin; 4. Dose does not exceed 1 container per month.
CP.PMN.244 Tazarotene (Arazlo, Fabior, Tazorac)	**VII. Initial Approval Criteria** A. **Plaque Psoriasis** (must meet all)**:** 1. Request is for Tazorac cream or gel; 2. Diagnosis of plaque psoriasis with body surface area involvement of ≤ 20%; 3. Prescribed by or in consultation with a dermatologist; 4. Request does not exceed 1 tube per month. **Approval duration: 12 months** B. **Acne Vulgaris** (must meet all)**:** 1. Diagnosis of acne vulgaris; 2. For Arazlo and Fabior requests only, member meets all of the following (a, b, and c): a. Member meets one of the following (i or ii): i. For Arazlo: age ≥ 9 years; ii. For Fabior: age ≥ 12 years; b. Documentation supports inability to use generic formulary topical tazarotene; c. Failure of generic formulary topical tretinoin and adapalene, unless clinically significant adverse effects are experienced or both are contraindicated; Request does not exceed 1 tube (Arazlo, Tazorac) or 1 can (Fabior) per month
CP.PMN.245 Opicapone (Ongentys)	**I. Initial Approval Criteria** **A. Parkinson's Disease** (must meet all): 1. Diagnosis of PD; 2. Prescribed by or in consultation with an neurologist;

	3. Age ≥ 18 years; 4. Member is experiencing "off" time (see Appendix D) on levodopa/carbidopa therapy; 5. Failure of two of the following adjunct drugs prescribed in combination with levodopa/carbidopa, each from different classes, unless contraindicated or clinically significant adverse effects are experienced:* a. MAO-B inhibitor: rasagiline; b. COMT inhibitor: entacapone (Comtan®/Stalevo®), tolcapone; c. Dopamine agonist: ropinirole/ropinirole ER, pramipexole/pramipexole ER; *Prior authorization may be required for the above agents 6. Prescribed in combination with levodopa/carbidopa; 7. Dose does not exceed 50 mg (1 capsule) per day.
CP.PHAR.475 Sacituzumab govitecan-hziy (Trodelvy)	**Initial Approval Criteria** C. **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 triple negative (i.e., estrogen receptor-, progesterone receptor-, and human epidermal growth factor receptor 2 [HER2]-negative) disease; 5. Failure of two prior regimens for metastatic disease *(see Appendix B)*; 6. Request meets one of the following (a or b):* i. Dose does not exceed 10 mg/kg on days 1 and 8 of each 21-day cycle; j. 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*
CP.PHAR.194 Macitentan (Opsumit)	**VIII. Initial Approval Criteria** **A. Pulmonary Arterial Hypertension** (must meet all)**:** 1. Diagnosis of PAH;

	2. Prescribed by or in consultation with a cardiologist or pulmonologist; 3. Failure of a calcium channel blocker (*see Appendix B*), unless member meets one of the following (a or b): a. Inadequate response or contraindication to acute vasodilator testing; b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced; 4. Failure of generic ambrisentan or bosentan, unless clinically significant adverse effects are experienced or both are contraindicated; Dose does not exceed 10 mg (1 tablet) per day
CP.PMN.216 Diazepam Nasal Spray (Valtoco**)**	**Initial Approval Criteria** A. **Epilepsy with Seizure Cluster Episodes** (must meet all)**:** 1. Diagnosis of partial or generalized epilepsy; 2. Prescribed by or in consultation with a neurologist; 3. Age ≥ 6 years; 4. Member is experiencing stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures); 5. Currently on a stable regimen of antiepileptic drugs (AEDs) (e.g., lamotrigine, gabapentin, topiramate, oxcarbazepine); 6. Medical justification supports inability to use Diastat® (e.g., contraindications to excipients in Diastat); 7. Dose does not exceed 2 doses per single episode (not to exceed 1 episode every 5 days or 5 episodes per month) (*refer to section V for age and weight specific dosing*).