Title: Q1 2021 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 12, 2021.

Table 1: Summary PDL Additions: Effective 3/1/2021

Drug	Action	Notes:
Arnuity Ellipta	Add	QL 1 per day
Fintepla	Add	3 Month Trial and Fail of Epidiolex
Qvar Redihaler	Add	Preferred Brand
Semglee	Add	Preferred Brand

Summary Policy Additions: Effective 3/01/2021

Posted at: https://www.mhsindiana.com/providers/resources/clinical-payment-policies.html

Policy/ Coverage Criteria Guideline	Revision Summary Description
CP.PHAR.40 Octreotide Acetate (Sandostatin, Sandostatin LAR, Bynfezia, Mycapssa)	Added new indication with same criteria: Advanced adrenal pheochromocytoma and paraganglioma added per NCCN.
CP.PHAR.59 Zoledronic Acid (Reclast, Zometa	Less restrictive criteria: The MM/solid tumor common criteria line item, at risk for skeletal related event, is removed for solid tumor and for MM is replaced with receiving or initiating therapy, chemo per NCCN;
CP.PHAR.63 Everolimus (Afinitor, Afinitor Disperz, Zortress)	Added new indication with no change to criteria. NCCN off lable criteria. For Hodgkin Lymphome, Waldenstrom Macroglobulenemia//Lymphoplasmacytic Lymphoplasmacytic, thymoma, or thymic carcinoma, unresectable or disease not responding to previous therapy added..
CP.PHAR.80 Vandetanib (Caprelsa)	Added new indication for off label use for lung cancer, recurrent, advanced, or metastatic disease. Need RET gene rearrangement.
CP.PHAR.91 Vemurafenib (Zelboraf)	Expanded Melanoma indications: recurrent/lymph node positive added to melanoma per NCCN; progressive/symptomatic Added to thyroid carcinoma with BRAF mutation per NCCN; Added

	Astrocytoma/oligodendroglioma indication with BRAF V600E mutation added per NCCN; CRC removed per NCCN;.
CP.PHAR.98 Ruxolitinib (Jakafi)	Add off label indications: For pediatric ALL; induction or consolidation therapy and additional mutations added per NCCN; New myeloid/lymphoid with mutations and essential thrombocytopenia indications step through or contraindicated hydroxyurea, peginterferon or anagrelide added per NCCN;.
CP.PHAR.100 Axitinib (Inlyta)	Expanded RCC indications to relapsed, stage IV, or metastatic disease added, add single-agent first-line therapy added per NCCN; For thyroid carcinoma,expanded to persistent disease added per NCCN;.
CP.PHAR.106 Enzalutamide (Xtandi)	Preferred formulation is the tablet.
CP.PHAR.111 Cabozantinib (Cabometyx, Cometriq)	Boxed warning removed; New NCCN off label indication added to list: GIST
CP.PHAR.119 Ramucirumab (Cyramza)	Added new indication NSCLC - EGRF mutation requirement added if therapy in combination with erlotinib..
CP.PHAR.121 Nivolumab (Opdivo)	Added new indication: FDA approved malignant pleural mesothelioma added. Added new FDA/NCCN indications: expanded melanoma, unresectable, metastatic, or lymph node positive disease added; For NSCLC, now allow single-agent therapy for tumor mutation burden biomarkers, combination therapy for RET rearrangement added, combination therapy changed from Yervoy and platinum doublet therapy to Yervoy plus/minus a platinum based regimen; Expanded incations for Classical Hodgkins Lymphome; relapsed, refractory or progressive disease added, post For HCC, Lenvima added as a prior therapy option; Off-label indications: Add Pediatric Hodgkin lymphoma and vulvar cancer
CP.PHAR.126 Ibrutinib (Imbruvica)	New NCCN indications: For Mantle Cell Lymphoma combination therapy with rituximab; For Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, transformation combination therapy with Opdivo and Keytruda. For Marginal Zone Lymphoma, added subtypes delineated for clarity, For cGVHD, trial

	requirement edited to require a systemic corticosteroid and an immunosuppressant.
CP.PHAR.166 Ferric Gluconate (Ferrlecit)	Added NCCN dosing limits for iron deficiency anemia without CKD.
CP.PHAR.167 Iron Sucrose (Venofer)	Added NCCN dosing limits for iron deficiency anemia without CKD
CP.PHAR.180 Eltrombopag (Promacta)	Criteria less restrict and allowing first or second line therapy as a single agent. , removed upper age limit for combination therapy.
CP.PHAR.188 Teriparatide (Forteo)	Removal of osteosarcoma black box warning per package insert update
CP.PHAR.200 Mepolizumab (Nucala) ^	New FDA indication: hypereosinophilic syndrome indication (HES); updated Appendix B and D.
CP.PHAR.235 Atezolizumab (Tecentriq)	Less restrictive: Added all forms of Hepatocellular Carcinoma.
CP.PHAR.306 Ofatumumab (Arzerra, Kesimpta) ^	New indication: New subcutaneous dosage form Kesimpta to the policy for the treatment of relapsing remitting or secondary progressive multiple sclerosis
CP.PHAR.319 Ipilimumab (Yervoy)	New indication added. FDA approved malignant pleural mesothelioma give with Opdivo. Expanded indication for melanoma unresectable/metastatic disease and lymph node positive disease New Indication Hepatocellular Cancer; Prior therapy with Lenvima and give concurrently with Opdivo per NCCN. No progress on other immunotherapy., Lenvima added as a prior therapy option per NCCN; Added ned indication: NSCLC, added and combination therapy and Mutation status per NCCN New drug options: Yervoy and platinum doublet therapy to Yervoy plus/minus a platinum based regimen to accommodate NCCN recommended uses;
CP.PHAR.333 Avelumab (Bavencio)	New Indication: Urothelial Carcinoma, recurrent disease added per NCCN, and platinum-based chemotherapy history added per label. New off label NCCN indication; gestational trophoblastic neoplasia prescribed as a single agent following failure of 2 systemic chemotherapeutic agents.

CP.PHAR.366 Acalabrutinib (Calquence)	Added new NCCN off label indications: Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. Prescribed as second line therapy.
CP.PHAR.368 Pemetrexed (Alimta, Pemfexy)	Less Restrictive: Added new NCCN criteria if member is intolerant to MTX: induction therapy offered for primary Central Nervous System lymphoma. Urothelial carcinoma off-label use removed per NCCN.
CP.PHAR.410 Bortezomib (Velcade)	Added new NCCN off label indications: AIDS-related Kaposi sarcoma and Pediatric Hodgkin Lymphoma use in combination with ifosafamide and vinorelbine.
CP.PHAR.412 Gilteritinib (Xospata)	Less Restrictive: Removed step therapy of Rydapt from Acute Myeloid Leukemia given increased Xospata
CP.PHAR.415 Ravulizumab-cwvz (Ultomiris)	Added requirement against concurrent use with Soliris
CP.PHAR.454 Avapritinib (Ayvakit)	Added new NCCN indication: Myeloid/Lymphoid Neoplasm has PDGFRA D842V mutation and t/f or contraindication of imatinib;.
CP.PHAR.455 Enfortumab Vedotin-ejfv (Padcev)	Less restrictive criteria by removing neoadjuvant therapy to encompass NCCN recommendation
CP.PHAR.456 Fam-trastuzumab deruxtecan-nxki (Enhertu)	Added new indication of recurrent breast cancer added per NCCN.
CP.PMN.03 DPP-4 inhibitors	Less restrictive criteria by removing step for combination DPP4/SGLT2 products
CP.PMN.22 Brand Name Override	Updated to include biosimilars: added language to require use of preferred biosimilars if available;.
CP.PMN.227 Edoxaban (Savaysa)	Added new NCCN indication with same criteria: venous thromboembolic disease recommendations;.

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.PMN.257 **Clascoterone (Winlevi)**	**I. Initial Approval Criteria** **A. Acne Vulgaris** (must meet all)**:** **1.** Diagnosis of acne vulgaris; **2.** Age ≥ 12 years; **3.** Failure of ≥ 2 of the following topical preparations, each from different medication classes, each used for ≥ 2 months, unless clinically significant adverse effects are experienced or all are contraindicated:

	4. Topical antibiotics: clindamycin, erythromycin; **5.** Topical anti-infectives: benzoyl peroxide; **6.** Topical retinoids: tretinoin; **7.** Dose does not exceed 60 grams (1 tube) per month.
CP.PHAR.516 **Rukobia (fostemsavir)**	**I. Initial Approval Criteria** **A. Human Immunodeficiency Virus** (must meet all)**:** 1. Diagnosis of HIV-1 infection; 2. Prescribed by or in consultation with an infectious disease or HIV specialist; 3. Age ≥ 18 years; 4. Failure of ≥ 3 month trial of one of the following at up to maximally indicated dose, unless clinically significant adverse effects are experienced or both are contraindicated: Fuzeon®, Selzentry® if CCR5 tropic; 5. Current (within the past 30 days) HIV ribonucleic acid viral load ≥ 200 copies/mL; 6. Prescriber attestation that Rukobia will be taken in combination with an optimized antiviral background regimen including one or more antiretroviral agents; Dose does not exceed 1200 mg (2 tablets) per day