

**Title:** Q4 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 October 13, 2020.

**Table 1: Summary PDL Additions: Effective 12/1/2020**

Drug	Action	Notes:
Ubrelevy	Update	Quantity limit of 10 tabs per month

**Summary Policy Additions: Effective 12/01/2020**

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

Antineoplastic Agents	
CP.PHAR.65 Imatinib (Gleevec)	Positive change. Add new diagnosis: AIDS-related KS: updated criteria to require concurrent use with antiretroviral therapy and failure of first line agents per NCCN guidelines; added immunologist as a new prescriber option per specialist feedback.
CP.PHAR.71 Lenalidomide (Revlimid)	Positive change. Add new diagnosis : AIDS-related KS: updated criteria to require concurrent use with antiretroviral therapy and failure of first line agents per NCCN guidelines;
CP.PHAR.78 Thalidomide (Thalomid)	Positive change. Add new diagnosis. AIDS-related KS: updated criteria to require concurrent use with antiretroviral therapy and failure of first line agents per NCCN guidelines;
CP.PHAR.79 Lapatinib (Tykerb)	Positive change. Added the following off-label criteria per NCCN recommendations: chordoma- added that Tykerb must be prescribed as a single agent; colorectal cancer- added that disease must also be BRAF wild type.
CP.PHAR.93 Bevacizumab (Avastin, Mvasi, Zirabev)	Removed AIDS-related Kaposi sarcoma as an off label use as it is no longer NCCN supported
CP.PHAR.119 Ramucirumab (Cyramza)	Positive change: Added new diagnosis: NSCLC with EGFR mutations; added criteria for NSCLC for use in combo with Erlotinib; added criteria for advanced esophageal, EGJ or gastric cancer allowing combination with fluorouracil and irinotecan per NCCN
CP.PHAR.125 Palbociclib (Ibrance)	Positive change: For breast cancer removed step, modified to allow first-line use with fulvestrant per NCCN category 1 recommendation; for retroperitoneal liposarcoma, modified to

	allow only unresectable disease per NCCN category 2A recommendation.
CP.PHAR.137 Ivosidenib (Tibsovo)	Positive change. New approved diagnosis: Added criteria for unresectable or metastatic biliary tract cancer per NCCN off label indication. Positive for IDH1 mutation.
CP.PHAR.138 Lenvatinib (Lenvima)	Positive change. Additional diagnosis: Added off-label criteria for ATC per NCCN. Step therapy Cometriq or Caprelsa or as single agent if cannot tolerate.
CP.PHAR.311 Belinostat (Beleodaq)	Positive change. Additional diagnosis: Added additional off-label indication cutaneous CD30+ T-cell lymphoma as a covered diagnosis as per NCCN
CP.PHAR.309 Carfilzomib (Kyprolis)	Positive change to an existing policy. New combination of medications: MM - FDA approved regimen added: in combination with Darzalex and dexamethasone, and NCCN recommended regimen added: in combination with dexamethasone and cyclophosphamide ± Thalomid.
CP.PHAR.317 Cetuximab (Erbix)	Positive change to use as single agent: Added criteria to HNSCC indication for use as single agent or in combination with platinum based therapy with 5-FU; added BRAF disease wild-type and for treatment in combination with Braftovi if BRAF V600E mutation position to colorectal indication as per NCCN
CP.PHAR.318 Eribulin mesylate (Halaven)	Positive change adding STS diagnosis: NCCN recommendations – added “advanced” designation to extremity/body wall and head/neck STS; removed “progressive” and added “recurrent or stage IV” designation to retroperitoneal/intra-abdominal STS; added “advanced or metastatic” designation to pleomorphic rhabdomyosarcoma; added additional STS subtype options: solitary fibrous tumor and UPS; added that Halaven should be used as subsequent therapy for all STS subtypes except angiosarcoma, solitary fibrous tumor, and UPS.
CP.PHAR.321 Panitumumab (Vectibix)	Positive change. New indication added: BRAF disease wild-type and for treatment in combination with Braftovi if BRAF V600E mutation for colorectal indication as per NCCN 2A off label indication.
CP.PHAR.355 Abemaciclib (Verzenio)	Allowing first line use: Modified to allow first-line use with fulvestrant per NCCN category 1 recommendation; added that member has not previously failed another CDK 4/6 inhibitor therapy.

CP.PHAR.358 Gemtuzumab (Mylotarg)	Pediatric extention. Updated age limit to 1 month from 18 years for new diagnosed AML as per FDA label.
CP.PHAR.387 Azacitidine (Vidaza)	Less restrictive: MDS, MF, AML criteria collapsed in to contain age greater than 18 years, FDA dosing or NCCN approved dosing.
CP.PHAR.439 Valrubicin (Valstar)	Revised criteria to removed step through BCG if shortage exists as per NCCN 2A;
CP.PHAR.479 Decitabine-Cedazuridine (Inqovi)	Less restrictive. New Medication to market and policy is positive addition. Dx: MDS, Greater than 18 year old. Inability to use Dacogen, Dosing: FDA or NCCN or .
CP.PHAR.507 Lomustine (Gleostine)	Less restrictive: Brain Tumor: Step through Temozolomide. Hodgkins Lymphoma: Step through initial chemotherapy regimen. NCCN and FDA approved dosing.
CP.PHAR.508 Tafasitamab-cxix (Monjuvi)	Diffuse Large B cell Lymphoma, 18 years of age and older; Prior chemo therapy with Revlimid, member not eligible for autologous stem cell transplant, FDA or NCCN dosing. Same as other agents in this therapeutic class.
<b>Other Therapeutic Classes</b>	
CP.PHAR.232 Onabotulinumtoxin A (Botox)	For chronic migraine, clarified requirement for use of two oral migraine preventative therapies that are from different therapeutic classes.
CP.PHAR.260 Rituximab (Rituxan, Ruxience, Truxima, Rituxan Hycela)	For NMOSD: added requirement against concurrent use with Soliris, Enspryng, or Uplizna; modified EDSS from $\leq 7$ to $\leq 8$ to align with Uplizna policy. Same as other agents in this class
CP.PHAR.97 Eculizumab (Soliris)	For NMOSD: added requirement against concurrent use with rituximab, Enspryng, or Uplizna. Same as other agents in this class
CP.PHAR.458 Inebilizumab-cdon (Uplizna)	Safety criteria per FDA labeling: added requirement that member does not have active HBV or TB since both are contraindications; added requirement against concurrent use with rituximab, Soliris, or Enspryng; Same as other agents in this class
CP.PHAR.58 Denosumab (Prolia Xgeva)	Positive change. NCCN added new diagnosis: prostate/breast fracture prevention, and systemic mastocytosis.
CP.PHAR.364 Guselkumab (Tremfya) ^	Added new diagnosis: PsA; references reviewed and updated.

CP.PHAR.385 Corticosteroid Intravitreal Implants (Iluvien, Ozurdex, Retisert, Yutiq)	Revised dosing frequency for Ozurdex from q6 months to q4 months per literature review, guideline recommendations, market analysis, and specialist feedback.
CP.PMN.80 Minocycline ER (Solodyn, Ximino, Minolira), Microspheres (Arestin), Foam (Zilxi)	Added Zilxi with step therapy of Minocycline and 4 week trial of a preferred oral tetracycline or contraindication. Positive change because adding contraindication if provider needs to skip step therapy.
CP.PHAR.136 Elagolix (Orilissa), elagolix-estradiol-norethindrone (OriaHnn) ^	Medical Necessity Criteria For Utilization Of A Nonpreferred Product and positive change. Non preferred but step through preferred products: For endometriosis, Step therapy of 3-month trial within the last year and non-contraceptive progestin. Removed t/f NSAID: Criteria added for new FDA-approved combination product and its indication: OriaHnn for management of heavy menstrual bleeding due to uterine fibroids. Step therapy of Estrogen-progestin contraceptive agent for 3 months.
CP.PMN.49 Pradaxa	Change step therapy to only Eliquis. Approved this PDL change last month.
CP.PMN.227 Savaysa	Change step therapy to only Eliquis. Approved this PDL change last month.
CP.PHAR.422 Inrebic	Step through Jakafi unless contraindicated. Positive change.
CP.PMN.86 Oxymetazoline (Rhofadol) Upneeq)	Positive change with pediatric extension. . New indications: Acquired blepharoptosis. Lowered age 13 years or older. Consultation of optometrist or ophthalmologist for initial approval, does not have congenital or mechanical ptosis, has peripheral vision lost, documentation of marginal reflux distance 1 being 2 mm or less
CP.PMN.90 Benznidazole	Allow use at any age; 60 days of therapy limitation to the current infection. Recommended by CDC and FDA
CP.PMN.164 Cannabidiol (Epidiolex) ^	Medical Necessity Criteria For Utilization Of A Nonpreferred Product and positive change. Criteria added for updated FDA indication: seizures associated with TSC; Updated pediatric age expansion to age $\geq$ 1 year for all indications.
CP.PHAR.505 Continuous Insulin Delivery Systems (V-Go, Omnipod)	Utilization Edit: V-Go 21 yo; Continuous insulin delivery system, or 3 daily injections of basal and bolus insulin, Suboptimal blood sugar control, Monitor BG 4 or more times per day for 6 months. V-Go 1 device per day. Omnipod 1 pod every 3 days.

CP.PHAR.506 Antithymocyte Globulin (Atgam, Thymoglobulin)	Kidney transplant rejection. Prophylaxis Thymoglobulin 7 doses. Treatment Thymoglobulin 14 doses or up to 42 days of Atgam with cyclosporine for Aplastic Anemia..
CP.PMN.251 Lactic acid-citric acid-potassium bitartrate (Phexxi)	Medical Necessity Criteria For Utilization Of A Nonpreferred Product: Prescribed for pregnancy prevention, Step through spermicide. Not currently used with vaginal ring products.
CP.PMN.252 Metoclopramide (Gimoti)	Diabetic gastroparesis, 18 years or older inability to use all other formulations of metoclopramide..
CP.PMN.253 Abametapir (Xeglyze)	Age 6 months or older, step through 2 PDL agents
CP.PMN.254 Budesonide-glycopyrrolate-formoterol fumarate (Breztri Aerosphere)	Step through 2 LABA, LAMA and ICS PDL agents.
CP.PMN.53 Off-Label Use	Positive change to simplify reviews. Removed criteria for drugs without existing coverage criteria and moved to separate policy per PA Added NCCN 2B as an acceptable level of evidence per Compliance.
CP.PMN.255 No Coverage Criteria	Positive change to simplify reviews. Step through 2 PDL agents, member has no contraindication to prescribed agent, Minimize any risk associated with boxed warning in product information, does not exceed FDA dosing.