

Title: Q2 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 April 14, 2020.

Table 1: Summary PDL Additions: Effective 05/01/2020

Drug	Action	Notes:
Generic Apriso (Mesalamine)	Add to PDL	No longer redirecting to Generic Lialda
Generic Delzicol (Mesalamine)	Add to PDL	No longer redirecting to Generic Lialda

Summary Policy Additions: Effective 08/01/2020

Policy	Notes:
CP.PHAR.50 Binimetinib (Mektovi)	2Q 2020 annual review: added NCCN compendium supported off-label use in colon and rectal cancers in combination with Braftovi and either Erbitux or Vectibix; references reviewed and updated.
CP.PHAR.60 Capecitabine (Xeloda)	2Q 2020 annual review: NCCN compendium-supported changes to occult primary and neuroendocrine tumors of the pancreas indications as capecitabine use as a single agent is supported for both of these indications; added NCCN compendium-supported uses of small bowel adenocarcinomas and thymomas and thymic carcinomas; added requirement for medical justification if brand Xeloda requested as generic available; references reviewed and updated.
CP.PHAR.65 Imatinib (Gleevec)	2Q 2020 annual review: GVHD NCCN recommended use added.
CP.PHAR.69 Sorafenib (Nexavar)	2Q 2020 annual review: added NCCN compendium-supported indication of ovarian cancers; references reviewed and updated.
CP.PHAR.71 Lenalidomide (Revlimid)	2Q 2020 annual review: per NCCN Compendium for MM maintenance therapy added option for use in combination with bortezomib; for MDS added MDS and myeloproliferative overlap neoplasms; added primary CNS lymphoma and AIDS-Related Kaposi Sarcoma to Section IF; references reviewed and updated.

CP.PHAR.74 Erlotinib (Tarceva)	2Q 2020 annual review: added quantity limits of 4 tablets per day; references reviewed and updated.
CP.PHAR.75 Bexarotene (Targretin Capsules, Gel)	2Q 2020 annual review: added bexarotene gel formulation and criteria; updated appendix D primary cutaneous lymphoma classification; references reviewed and updated.
CP.PHAR.77 Temozolomide (Temodar)	2Q 2020 annual review: updated NCCN compendium-supported uses; condensed similar criteria for glioblastoma and anaplastic astrocytoma; added requirement for medical justification if brand Temodar requested as generic is available; references reviewed and updated.
CP.PHAR.105 Bosutinib (Bosulif)	2Q 2020 annual review: adult age restriction removed from ALL per NCCN; contraindication added. references reviewed and updated.
CP.PHAR.107 Regorafenib (Stivarga)	2Q 2020 annual review: added NCCN compendium-supported indication of osteosarcoma; references reviewed and updated.
CP.PHAR.116 Pomalidomide (Pomalyst)	2Q 2020 annual review: added NCCN compendium-supported indication of primary CNS lymphoma; references reviewed and updated.
CP.PHAR.120 Sipuleucel-T (Provenge)	2Q 2020 annual review: added urologist as prescriber option to criteria; removed dose quantity restriction from approval duration and added it to criteria, references reviewed and updated.
CP.PHAR.121 Nivolumab (Opdivo)	Added NCCN compendium-supported indication of uveal melanoma as a single agent or in combination with Yervoy.
CP.PHAR.78 Thalidomide (Thalomid)	2Q 2020 annual review: added NCCN compendium-supported indication of active idiopathic MCD in section I.D.; references reviewed and updated.
CP.PHAR.79 Lapatinib (Tykerb)	Added NCCN compendium-supported use of colorectal cancer in combination with trastuzumab; references reviewed and updated.
CP.PHAR.125 Palbociclib (Ibrance)	Added that member has not previously failed another CDK 4/6 inhibitor therapy for breast cancer.
CP.PHAR.127 Encorafenib (Braftovi)	2Q 2020 annual review: added NCCN compendium supported off-label use in colon and rectal cancers in combination with Mektovi and either Erbitux or

	Vectibix; added maximum quantity for all indications; references reviewed and updated.
CP.PHAR.176 Paclitaxel protein-bound (Abraxane)	2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and triple-negative breast cancer; references reviewed and updated.
CP.PHAR.227 Pertuzumab (Perjeta)	2Q 2020 annual review: added NCCN compendium-supported use of colorectal cancer; references reviewed and updated.
CP.PHAR.228 Trastuzumab Biosimilars Trastuzumab-Hyaluronidase	2Q 2020 annual review: added NCCN compendium-supported indications of colon and rectal cancer; incorporated NCCN compendium-supported indication of leptomeningeal metastases from HER2-positive breast cancer into breast cancer criteria; added appendix D: Added biosimilar preferencing, added reference to appendix D within criteria; references reviewed and updated.
CP.PHAR.236 Darbepoetin alfa (Aranesp)	2Q 2020 annual review. redirection to biosimilar ESA Retacrit per existing clinical guidance; for anemia with chemotherapy, modified diagnosis requirement to confirm request is for use in solid or non-myeloid malignancies in members receiving myelosuppressive chemotherapy without curative intent consistent with NCCN and ASCO recommendations; references reviewed and updated.
CP.PHAR.237 Epoetin alfa (Epogen, Procrit), Epoetin alfa-epbx (Retacrit)	2Q 2020 annual review: for anemia with chemotherapy, modified diagnosis requirement to confirm request is for use in solid or non-myeloid malignancies in members receiving myelosuppressive chemotherapy without curative intent consistent with NCCN and ASCO recommendations; references reviewed and updated.
CP.PHAR.238 Methoxy polyethylene glycol-epoetin beta (Mircera)	2Q 2020 annual review: added Commercial line of business (retired CP.CPA.322); added redirection to biosimilar ESA Retacrit per existing clinical guidance; Section IA, Ib clarified Age > or = 5 years to Less than or = 17 years; references reviewed and updated
CP.PHAR.239 Dabrafenib (Tafinlar)	2Q 2020 annual review: added NCCN supported off-label uses in colon and rectal cancers; added NCCN supported off-label dosing verbiage; for NSCLC added advanced disease; references reviewed and updated.

CP.PHAR.242 Adalimumab (Humira), Humira Biosimilars	2Q 2020 annual review: for UC, revised redirection from AZA, 6-MP, and ASA to corticosteroids and added requirement of Mayoscore of at least 6; references reviewed and updated.
CP.PHAR.243 Alemtuzumab (Lemtrada)	2Q 2020 annual review: added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; clarified that only 1 treatment course may be approved per authorization; references reviewed and updated.
CP.PHAR.250 Etanercept (Enbrel)	2Q 2020 annual review: no significant changes; added dose rounding guidelines for IV weightbased dosing for PJIA and pediatric PsO; references reviewed and updated.
CP.PHAR.251 Fingolimod (Gilenya)	2Q 2020 annual review: clarified max dosing requirement per body weight; added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon reauthorization; modified Commercial initial approval duration from Length of Benefit to 6 months; modified all continued approval duration to 6 months for the first re-authorization and 12 months for second/subsequent re-authorizations; references reviewed and updated.
CP.PHAR.252 Glatiramer (Copaxone, Glatopa)	2Q 2020 annual review: added requirements for documentation of baseline relapses/EDSS; references reviewed and updated.
CP.PHAR.253 Golimumab (Simponi, Simponi Aria)	2Q 2020 annual review: for UC, revised redirection from AZA, 6-MP, ASA to systemic corticosteroids, added requirement for Mayo score of at least 6; references reviewed and updated.
CP.PHAR.254 Infliximab (Remicade, Renflexis, Inflectra)	2Q 2020 annual review: for UC, revised redirection from AZA, 6-MP, ASA to systemic corticosteroids, and added requirement for Mayo score of at least 6; added dose rounding guidelines for all indications; references reviewed and updated.
CP.PHAR.255 Interferon beta-1a (Avonex, Rebif)	2Q 2020 annual review: added requirements for documentation of baseline relapses/EDSS
CP.PHAR.256 Interferon beta-1b	2Q 2020 annual review: added CIS re-directions for Extavia added requirements for documentation of baseline relapses/EDSS references reviewed and updated.

(Betaseron, Extavia)	
CP.PHAR.258 Mitoxantrone (Novantrone)	2Q 2020 annual review: ALL: added off-label criteria for pediatric ALL per NCCN; MS: added requirements for documentation of baseline relapses/EDSS references reviewed and updated.
CP.PHAR.259 Natalizumab (Tysabri)	2Q 2020 annual review: MS: added CIS re-directions; added requirements for documentation of baseline relapses/EDSS; references reviewed and updated.
CP.PHAR.260 Rituximab (Rituxan, Ruxience, Truxima, Rituxan Hycela)	2Q 2020 annual review: updated newly approved Preferencing biosimilar. FDA-indications for Truxina: RA, MPA, GPA; added NCCN 2A supported off-label use primary CNS lymphoma; added requirement for aggressive mature B-cell lymphoma for pediatric patients; added requirement for CD20 positivity for ALL off-label use per NCCN; for
CP.PHAR.261 Secukinumab (Cosentyx)	2q 2020 annual review; no significant changes; for AS, added requirement of inadequate response to a > or = 3 consecutive month trial of 150 mg every 4 weeks for increase maintenance dosing of 300 RA, removed mg every 4 weeks per updated PI; references reviewed and updated.
CP.PHAR.262 Teriflunomide (Aubagio)	2Q 2020 annual review: added requirements for documentation of baseline relapses/EDSS; references reviewed and updated.
CP.PHAR.263 Tocilizumab (Actemra)	2Q 2020 annual review: allowed refractory CRS related to blinatumomab therapy per NCCN; added off-label use criteria for Castleman's disease per NCCN; references reviewed and updated.
CP.PHAR.265 Vedolizumab (Entyvio)	2Q 2020 annual review; for UC, revised redirection from AZA, 6-MP, and ASA to systemic corticosteroids, revised redirection from Humira and another TNFi to Humira or Simponi, and added Mayo score requirement of at least 6; references reviewed and updated.
CP.PHAR.267 Tofacitinib (Xeljanz Xeljanz XR)	2Q 2020 annual review: for UC, removed requirement for immediate-release formulation, removed redirection to ASA, 6-MP, AZA, added requirement for Mayo score of at least 6, added a trial of corticosteroids; references reviewed and updated.

CP.PHAR.271 Peginterferon beta-1a (Plegridy)	2Q 2020 annual review: added requirements for documentation of baseline relapses/EDSS; references reviewed and updated.
CP.PHAR.273 Vismodegib (Erivedge)	2Q 2020 annual review: NCCN recommended use added for medulloblastoma; references reviewed and updated.
CP.PHAR.287 Obeticholic acid (Ocaliva)	Added preemptive criteria for the pending FDA approval of NASH indication;
CP.PHAR.310 Daratumumab (Darzalex)	Criteria added for new FDA MM indication: in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed MM patients who are eligible for ASCT; NCCN MM recommendation added for Darzalex as subsequent therapy in combination with dexamethasone and carfilzomib; NCCN recommendation added for relapsed or refractory amyloidosis; references reviewed and updated.
CP.PHAR.316 Cabazitaxel (Jevtana)	2Q 2020 annual review: added requirement for concurrent steroid use; references reviewed and updated.
CP.PHAR.319 Ipilimumab (Yervoy)	2Q 2020 annual review: added NCCN compendium-supported indications of small bowel adenocarcinoma and uveal melanoma; condensed NCCN compendium-supported indications into one subsection; references reviewed and updated.
*CP.PHAR.322 Pembrolizumab (Keytruda)	Criteria added for new FDA indication: NMIBC-CIS; urologist added for UC; removed 50 mg powder single-dose vial formulation; references reviewed and updated.
CP.PHAR.335 Ocrelizumab (Ocrevus)	2Q 2020 annual review: modified CIS re-direction to include glatiramer; added requirements for documentation of baseline relapses/ references reviewed and updated.
CP.PHAR.339 Durvalumab (Imfinzi)	2Q 2020 annual review: NCCN recommended use for SCLC added; references reviewed and updated.
CP.PHAR.378 Ibalizumab-uiyk (Trogarzo)	2Q 2020 annual review: modified required resistance to an agent from 4 classes to 3 classes and required trials from both Fuzeon and Selzentry to either Fuzeon or Selzentry per pivotal trial inclusion criteria and to

	better allow formation of a viable regimen; references reviewed and updated.
CP.PHAR.406 Lorlatinib (Lorbrena)	2Q 2020 annual review: per NCCN Compendium added Xalkori as a possible redirect option for ALK-positive disease; added Rozlytrek as a possible redirect option for ROS1-positive disease; added quantity limit of 3 tablets to allow for dose adjustments; references reviewed and updated.
CP.PHAR.422 Cladribine (Mavenclad)	2Q 2020 annual review: added requirements for documentation of baseline relapses; references reviewed and updated.
CP.PHAR.427 Siponimod (Mayzent)	2Q 2020 annual review: added requirements for documentation of baseline relapses/EDSS; references reviewed and updated.
CP.PHAR.432 Tafamidis (Vyndaqel, Vyndamax)	Cardiac scintigraphy added as a tissue biopsy alternative for ATTR-CM; references reviewed and updated.
CP.PMN.127 Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys)	Per FDA labeling; modified criteria to require member be euthyroid, clarified systemic corticosteroid trial required, clarified 8 total infusions allowed and included requirement in initial approval criteria; for continued therapy added additional response criteria requiring > or = 2 mm reduction in proptosis, removed requirement that TED remain active to allow completion of treatment course in members responding positively to therapy; for continued therapy added requirement to validate member does not require surgical ophthalmological intervention; references reviewed and updated.
*CP.PMN.220 Peanut allergen powder (Palforzia)	Drug is now FDA approved
CP.PMN.154 Isavuconazonium (Cresemba)	2Q 2020 annual review; added t/f of voriconazole to criteria for invasive aspergillosis; separated invasive mucormycosis from invasive aspergillosis; references reviewed and updated.
CP.PHAR.93	Revised Avastin redirection to Mvasi or Zirabev for non-ophthalmology uses

Bevacizumab (Avastin, Mvasi, Zirabev)	
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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>

Tazverik Policy CP.PHAR.452	<p>I. Initial Approval Criteria Epithelioid Sarcoma (must meet all):</p> <ol style="list-style-type: none"> 1. Diagnosis of ES; 2. Prescribed by or in consultation with an oncologist; 3. Age \geq 16 years; 4. Disease is metastatic or locally advanced, and not amenable to complete resection; 5. Tumor demonstrates loss of INI1 gene expression through inactivation, deletion, or mutation of the INI1 (SMARCB-1) gene; 6. Tazemetostat is prescribed as monotherapy; 7. Request meets one of the following (a or b):* <ol style="list-style-type: none"> a. Dose does not exceed 800 mg twice daily; 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
Ubrogepant (Ubrelvy) CP.PHAR.220	<p>I. Initial Approval Criteria Migraines (must meet all):</p> <ol style="list-style-type: none"> 1. Diagnosis of migraine headaches; 2. Age \geq 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 contraindicated or clinically significant adverse effects are experienced; 4. For requests for monthly quantities > 1 box of 6 tablets per month, member meets one of the following (a or b): <ol style="list-style-type: none"> a. Failure of TWO prophylactic migraine medications, unless clinically significant adverse effects are experienced or all are contraindicated (<i>see Appendix B</i>); b. Member is being treated by or in consultation with a neurologist or a headache specialist; 5. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™); 6. Dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

<p>Zanubrutinib (Brukinsa) Policy CP.PHAR.467</p>	<p>II. Initial Approval Criteria Mantle Cell Lymphoma (must meet all):</p> <ol style="list-style-type: none"> 1. Diagnosis of MCL; 2. Prescribed by or in consultation with an oncologist or hematologist; 3. Age \geq 18 years; 4. Member has received at least one prior therapy (see <i>Appendix B</i>); 5. Request meets one of the following (a or b):* <ol style="list-style-type: none"> a. Dose does not exceed 320 mg (4 capsules) per day; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (<i>prescriber must submit supporting evidence</i>). <p><i>*Prescribed regimen must be FDA-approved or recommended by NCCN</i></p>
<p>Clinical Policy: Givosiran (Givlaari)</p> <p>Reference Number: CP.PHAR.457 Effective Date: 03.01.20 Last Review Date: 02.20 Line of Business: Commercial, HIM, Medicaid</p>	<p>III. Initial Approval Criteria</p> <p>A. Acute Hepatic Porphyria (must meet all):</p> <ol style="list-style-type: none"> 6. Diagnosis of one of the following AHP subtypes with confirmatory genetic testing (a, b, c, or d): <ol style="list-style-type: none"> a. Acute intermittent porphyria (AIP) and a positive HMBS (aka PBGD) mutation; b. Hereditary coproporphyria (HCP) and a positive CPOX mutation; c. Variegate porphyria (VP) and a positive PPOX mutation; d. ALA dehydratase-deficiency (ALAD) porphyria and a positive ALAD mutation; 7. Prescribed by or in consultation with a gastroenterologist, hematologist, or neurologist; 8. Age \geq 18 years; 9. History of at least a four-fold increase of 5-aminolevulinic acid (ALA) or porphobilinogen (PBG) measured as mg/g creatinine using a random urine sample (<i>see Appendix E</i>); 10. History of \geq 2 porphyria attacks in a 6-month period requiring hospitalization, urgent healthcare visit, or intravenous Panhematin[®] (hemin for injection) administration at home, and (a or b): <ol style="list-style-type: none"> a. The porphyria attacks occurred within the last 6 months; b. The porphyria attacks occurred in any 6-month period and member is currently receiving prophylactic

	<p>Panhematin therapy (e.g., once or twice a week on a regular basis); <i>*Prior authorization may be required.</i></p> <p>11. Panhematin, as a prophylactic treatment, is not prescribed concurrently with Givlaari (note: use of Panhematin for treatment of acute porphyria attacks while taking Givlaari is appropriate); Dose does not exceed 2.5 mg/kg once monthly</p>
<p>Clinical Policy: Cenobamate (Xcopri)</p> <p>Reference Number: CP.PMN.231</p>	<p>IV. Initial Approval Criteria</p> <p>A. Partial-Onset Seizures (must meet all):</p> <p>12. Diagnosis of partial-onset seizures; 13. Prescribed by or in consultation with a neurologist; 14. Age ≥ 18 years; 15. Failure of two preferred anticonvulsants indicated for partial seizures (<i>see Appendix B for examples</i>), unless contraindicated or clinically significant adverse effects are experienced; Dose does not exceed 400 mg (2 tablets) per day</p>
<p>Clinical Policy: Acalabrutinib (Calquence)</p> <p>Reference Number: CP.PHAR.366</p>	<p>V. Initial Approval Criteria</p> <p>A. Mantle Cell Lymphoma (must meet all):</p> <p>16. Diagnosis of MCL; 17. Prescribed by or in consultation with an oncologist or hematologist; 18. Age ≥ 18 years; 19. Member has received at least one prior therapy* (<i>see Appendix B</i>); <i>*Prior authorization may be required</i></p> <p>20. Request meets one of the following (a or b):*</p> <p>a. Dose does not exceed 400 mg (4 capsules) per day; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (<i>prescriber must submit supporting evidence</i>). <i>*Prescribed regimen must be FDA-approved or recommended by NCCN.</i></p> <p>B. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (must meet all):</p> <p>1. Diagnosis of CLL or SLL; 2. Prescribed by or in consultation with an oncologist or hematologist; 3. Age ≥ 18 years;</p>

	<p>4. Calquence is prescribed in one of the following ways (a or b):*</p> <ul style="list-style-type: none"> a. First-line therapy as a single agent or in combination with Gazyva[®]; b. Subsequent therapy as a single agent for relapsed or refractory disease, and (i and ii): <ul style="list-style-type: none"> i. Member has received at least one prior therapy (see Appendix B); ii. If refractory to Imbruvica[®], member does not have a BTK C481S mutation; <p><i>*Prior authorization may be required</i></p> <p>5. Request meets one of the following (a or b):*</p> <ul style="list-style-type: none"> a. Dose does not exceed 400 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). <p><i>*Prescribed regimen must be FDA-approved or recommended by NCCN</i></p>
<p>Clinical Policy: Edoxaban (Savaysa)</p> <p>Reference Number: CP.PMN.227</p>	<p>VI. Initial Approval Criteria</p> <p>A. Non-Valvular Atrial Fibrillation, Deep Venous Thrombosis, Pulmonary Embolism (must meet all):</p> <ul style="list-style-type: none"> 21. Prescribed for one of the following conditions (a or b): <ul style="list-style-type: none"> a. Reduction of the risk of stroke and systemic embolism in member with NVAf; b. Treatment of DVT or PE; 22. Failure of Eliquis[®] and Xarelto[®], each used for ≥ 30 days at up to maximally indicated doses, unless both are contraindicated or clinically significant adverse effects are experienced; 23. If member has NVAf, recent (within the past 90 days) creatinine clearance (CrCl) is ≤ 95 mL/min; 24. Dose does not exceed 60 mg (1 tablet) per day.
<p>Clinical Policy: Fluticasone/Vilanterol (Breo Ellipta)</p> <p>Reference Number: CP.PMN.229</p>	<p>VII. Initial Approval Criteria</p> <p>A. Asthma and Chronic Obstructive Pulmonary Disease (must meet all):</p> <ul style="list-style-type: none"> 25. Diagnosis of asthma or COPD; 26. Age ≥ 18 years; 27. Failure of fluticasone/salmeterol (generic Advair Diskus[®]) or budesonide/formoterol (generic Symbicort[®]) at up to

	<p>maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;</p> <p>28. Dose does not exceed (a or b):</p> <ol style="list-style-type: none"> a. Asthma: 1 inhalation of 200 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days); b. COPD: 1 inhalation of 100 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days).
<p>Clinical Policy: Reference Number: CP.PHAR.242 Adalimumab (Hu Clinical Policy: Adalimumab (Humira), Adalimumab-atto (Amjevita), Adalimumab-adbm (Cyltezo), Adalimumab-bwwd (Hadlima), Adalimumab-adaz (Hyrimoz)mira), Adalimumab-adaz (Hyrimoz)</p>	<p>VIII. Initial Approval Criteria</p> <p>A. Rheumatoid Arthritis (must meet all):</p> <ol style="list-style-type: none"> 1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (<i>see Appendix G</i>); 2. Prescribed by or in consultation with a rheumatologist; 3. Age \geq 18 years; 4. Member meets one of the following (a or b): <ol style="list-style-type: none"> a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; b. If intolerance or contraindication to MTX (<i>see Appendix D</i>), failure of a \geq 3 consecutive month trial of at least ONE conventional disease-modifying antirheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 5. Failure of at least TWO of the following, each used for \geq 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel[®], Kevzara[®], Xeljanz[®]/Xeljanz XR[®]; <i>*Prior authorization is required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR</i> 6. Documentation of baseline clinical disease activity index (CDAI) score (<i>see Appendix H</i>); 7. Dose does not exceed 40 mg every other week. <p>B. Polyarticular Juvenile Idiopathic Arthritis (must meet all):</p> <ol style="list-style-type: none"> 1. Diagnosis of PJIA; 2. Prescribed by or in consultation with a rheumatologist; 3. Age \geq 2 years; 4. Member meets one of the following (a or b): <ol style="list-style-type: none"> a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated

	<p>or clinically significant adverse effects are experienced;</p> <p>b. If intolerance or contraindication to MTX (see <i>Appendix D</i>), failure of a ≥ 3 consecutive month trial of sulfasalazine or leflunomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;</p> <p>5. Failure of ≥ 3 consecutive months trial of Enbrel, unless contraindicated or clinically significant adverse effects are experienced; <i>*Prior authorization is required for Enbrel</i></p> <p>6. Dose does not exceed one of the following (a, b, or c):</p> <p>a. Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week;</p> <p>b. Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week;</p> <p>c. Weight ≥ 30 kg (66 lbs): 40 mg every other week.</p> <p>C. Psoriatic Arthritis (must meet all):</p> <p>1. Diagnosis of PsA;</p> <p>2. Prescribed by or in consultation with a dermatologist or rheumatologist;</p> <p>3. Age ≥ 18 years;</p> <p>4. Failure of at least THREE of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel[®], Otezla[®], Simponi[®]/Simponi Aria[®], Taltz[®], Xeljanz[®]/Xeljanz XR[®]; <i>*Prior authorization is required for Enbrel, Otezla, Simponi/Simponi Aria, Taltz, Xeljanz/Xeljanz XR</i></p> <p>5. Dose does not exceed 40 mg every other week.</p> <p>D. Ankylosing Spondylitis (must meet all):</p> <p>1. Diagnosis of AS;</p> <p>2. Prescribed by or in consultation with a rheumatologist;</p> <p>3. Age ≥ 18 years;</p> <p>4. Failure of at least TWO NSAIDs at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;</p> <p>5. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia[®], Enbrel, Taltz;</p>
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*Prior authorization is required for Cimzia, Enbrel, and Taltz

6. Dose does not exceed 40 mg every other week.

E. Crohn's Disease (must meet all):

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age \geq 6 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Medical justification supports inability to use immunomodulators (*see Appendix E*);
5. Dose does not exceed one of the following (a or b):
 - a. Adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29;
 - b. Pediatrics (i or ii):
 - i. Weight 17 kg (37 lbs.) to < 40 kg (88 lbs.): 80 mg on Day 1 and 40 mg on Day 15, followed by maintenance dose of 20 mg every other week starting Day 29;
 - ii. Weight \geq 40 kg (88 lbs): 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29.

F. Ulcerative Colitis (must meet all):

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age \geq 18 years;
4. Documentation of a Mayo Score \geq 6 (*see Appendix F*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29.

G. Plaque Psoriasis (must meet all):

1. Diagnosis of PsO;

2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (see *Appendix D*), failure of a \geq 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 \geq 3 consecutive month trial of Taltz, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for Taltz*
6. Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.

H. Hidradenitis Suppurativa (must meet all):

1. Diagnosis of HS;
2. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
3. Age \geq 12 years;
4. Documentation of Hurley stage II or stage III (see *Appendix D*);
5. Failure of a \geq 3 consecutive month trial of TWO of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin);
 - b. Oral retinoids;
 - c. Hormonal treatment;
6. Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every week starting Day 29.

I. Uveitis (must meet all):

1. Diagnosis of non-infectious intermediate, posterior or panuveitis;
2. Prescribed by or in consultation with an ophthalmologist or rheumatologist;

	<ol style="list-style-type: none">3. Age \geq 2 years;4. Failure of a \geq 2 week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;5. Failure of a trial of a non-biologic immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;6. Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.
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