Effective Date: 07/01/22

Buckeye Health Plan
Medicaid Criteria Updates –Q2 2022

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Policy/ Coverage Criteria Guideline	Applicable Business	Revision Summary Description
Clinically Significant Change(s)		
CP.PHAR.50 Binimetinib (Mektovi)	Commercial, HIM, Medicaid	2Q 2022 annual review: for melanoma, added adjuvant therapy category 2A indication per NCCN; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.58 Denosumab (Prolia Xgeva)	Commercial, HIM, Medicaid	For osteoporosis added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy.
CP.PHAR.60 Capecitabeine (Xeloda)	HIM, Medicaid	2Q 2022 annual review: added "maintenance therapy" and "unresponsive to preoperative systemic therapy" uses of Xeloda in breast cancer per NCCN; collapsed off-label criteria for neuroendocrine tumor of the pancreas into the off-label criteria set; WCG.CP.PHAR.60 was retired and initial approval duration was consolidated to 6 months; references reviewed and updated.
CP.PHAR.64 Topotecan (Hycamtin)	Commercial, HIM, Medicaid	2Q 2022 annual review: revisions made per FDA label and/or NCCN recommendations – for ovarian cancer, expanded coverable diagnoses to include additional types of ovarian cancer as well as fallopian tube and primary peritoneal cancer and added requirement for use as a single agent or in combination with bevacizumab or sorafenib; for cervical cancer, added requirement for use in combination with cisplatin or paclitaxel, or as a single agent as second-line or subsequent therapy; for off-label uses, removed primary CNS lymphoma and added specific requirements for use in Ewing sarcoma, osteosarcoma, endometrial sarcoma, and rhabdomyosarcoma; modified Commercial approval duration for capsules from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.

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CP.PHAR.65 Imatinib (Gleevec)	Commercial, HIM, Medicaid	2Q 2020 annual review: HIM nonformulary language removed; GVHD NCCN recommended use added; Continued Therapy authorization duration changed to 12 months for consistency with other oral oncology agents; added requirement for use of generic version in section II per Ambetter director's request; references reviewed and updated.
CP.PHAR.68 Gefitinib (Iressa)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.69 Sorafenib (Nexavar)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; added oral oncology generic redirection if available language per template; per NCCN for RCC added additional diagnosis options for relapsed or stage IV disease, for DTC added additional diagnosis options for unresectable or persistent disease, for AML removed requirement that disease is relapsed or refractory as Nexevar can be used for induction, for AML added additional option for use as a single agent for maintenance therapy for member in remission post-allogeneic stem cell transplantation, for soft tissue sarcoma clarified desmoid tumors requests should be used as single-agent therapy, for GIST added Sprycel as a possible prior therapy option, added off-label criteria set for lymphoid, myeloid or mixed lineage neoplasms; references reviewed and updated.
CP.PHAR.71 Lenalidomide (Revlimid)	Commercial, HIM, Medicaid	2Q 2022 annual review: per NCCN added additional use in combination with Monjuvi for MZL and FL, for myelofibrosis-associated anemia corrected requirements for ≥ 500 vs < 500 (previously was > 500 vs ≤ 500), added off-label use for Langerhans cell histiocytosis as a single agent therapy, modified KS requirements to allow use in non-AIDs related KS, revised CLL/SLL to remove options for first-line therapy; removed mycosis fungoides/Sezary syndrome off-label use; removed primary cutaneous CD30+ T-cell lymphoproliferative disorders off-label use; modified peripheral T-cell lymphoma to allow use as initial palliative intent therapy; references reviewed and updated.

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CP.PHAR.72 Dasatinib (Sprycel)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.72 to be retired and approval durations consolidated to 6 months; per NCCN for CML and ALL added exclusions for mutations that are contraindicated, for GIST added Ayvakit and removed Sutent and Stivarga as prior therapy options; for CML, AML, chordoma, and myeloid/lymphoid neoplasms added that member has contraindication, intolerance, or disease progression on imatinib or allowed by-passing of redirection if state regulations do not allow step therapy in certain oncology settings; references reviewed and updated.
CP.PHAR.73 Sunitinib (Sutent)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.73 to be retired and approval durations consolidated to 6 months; per NCCN added additional off-label uses in GIST for combination therapy with everolimus and SDH mutation positive disease, for GIST with disease progression or intolerance to imabinib clarified request is for single agent therapy, for differentiated and medullary thyroid carcinoma revised requirement of failure of two FDA approved therapies to more closely align with NCCN Compendium which recommends Sutent if clinical trials or other systemic therapies are not available or appropriate; for RCC initial authorization clarified in adjuvant therapy request is for up to nine cycles consistent with the current requirement for continuation of therapy; references reviewed and updated.
CP.PHAR.74 Erlotinib (Tarceva)	Commercial, HIM, Medicaid	2Q 2022 annual review: for bone cancer added single-agent therapy criterion per NCCN; WCG.CP.PHAR.74 was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.75 Bexarotene (Targretin Capsules, Gel)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; for Section IA, clarified this applies to

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		bexarotene capsule requests; for continuation of therapy added requirement for Targretin capsule request, member must use generic bexarotene capsules; references reviewed and updated.
CP.PHAR.76 Nilotinib (Tasigna)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.76 to be retired and approval durations consolidated to 6 months; per NCCN for CML and ALL added exclusions for mutations that are contraindicated, for GIST added Quinlock and Sprycel as additional prior therapy options, added criteria set for off-label use in myeloid/lymphoid neoplasms; for CML, AML, and myeloid/lymphoid neoplasms added that member has contraindication, intolerance, or disease progression on imatinib or allowed by-passing of redirection if state regulations do not allow step therapy in certain oncology settings; added generic redirection language per template for oral oncology products; references reviewed and updated.
CP.PHAR.77 Temozolomide (Temodar)	HIM, Medicaid	2Q 2022 annual review: Per NCCN, added indication of low-grade (WHO grade 1 or II) recurrent or progressive disease, removed "recurrent" from brain metastases indication, added mucosal melanoma, modified cutaneous melanoma indication use from second line to subsequent therapy, and added neuroendocrine tumor of the lung; WCG.CP.PHAR.77 was retired and initial approval duration was consolidated to 6 months; references reviewed and updated.
CP.PHAR.78 Thalidomide (Thalomid)	Commercial, HIM, Medicaid	2Q 2022 annual review: added language for oral oncology generic redirection if available per template; for myeloproliferative neoplasms added notation that Retacrit is the preferred ESA; per NCCN modified KS requirements to allow use in non-AIDs related KS, added off-label criteria set for histiocytic neoplasms; WCG.CP.PHAR.78 to be retired and approval durations consolidated to 6 months initial and 12 months for continuation of therapy; added off-label use for aphthous stomatitis or ulcers per previous coverage in WCG policy; references reviewed and updated.

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CP.PHAR.90 Crizotinib (Xalkori)	Commercial, HIM, Medicaid	2Q 2022 annual review: for NSCLC, clarified criteria as MET as exon 14 skipping or high-level MET amplification positive per NCCN; added hematologist as specialist in ALCL; added criterion for Xalkori single-agent therapy for NSCLC, ALCL, and inflammatory myofibroblastic tumor per NCCN; added histiocytic neoplasms indications per NCCN category 2A; WCG.CP.PHAR.90 was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.105 Bosutinib (Bosulif)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approv al duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.105 to be retired and approval durations consolidated to 6 months initial and 12 months for continuation of therapy; for imatinib redirection added by-passing of redirection if state regulations do not allow step therapy in Stage IV or metastatic cancer settings; references reviewed and updated.
CP.PHAR.107.Regorafenib (Stivarga)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.107 to be retired and approval durations consolidated to 6 months initial and 12 months continuation of therapy; per NCCN added criteria set for off-label use in glioblastoma; per template added generic oral oncology redirection if available language; references reviewed and updated.
CP.PHAR.108 Omecetaxine (Synribo)	Commercial, HIM, Medicaid	2Q 2022 annual review: added additional prior therapy option requirement for T315I mutation that member has received prior treatment with Iclusig and Scemblix as other TKIs are contraindicated in this specific mutation; references reviewed and updated.
CP.PHAR.112.Ponatinib (Iclusig)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.112 to be retired and approval durations consolidated to 6 months initial and 12 months for continuation of therapy; added generic oral oncology redirection if available language; per NCCN for CML clarified

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		2TKI requirement is for chronic phase CML and added additional option for accelerated or blast phase CML for members whom no other TKI therapy is indicated, for ALL removed 2 TKI requirement and replaced with requirement that either member has BCR-ABL T315I mutation or no other TKI therapy is indicated, added off-label criteria set for lymphoid, myeloid or mixed lineage neoplasms with redirection to imatinib for ABL1 rearrangement positive unless state regulations do not allow step therapy in certain oncology settings; references reviewed and updated.
CP.PHAR.116 Pomalidomide (Pomalyst)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; added oral oncology generic (if available) redirection language; per NCCN for KS applied requirement for failure of liposomal doxorubicin and paclitaxel to non-AIDS-related KS, for primary CNS lymphoma added additional use for induction therapy if unable to use high-dose methotrexate; references reviewed and updated.
CP.PHAR.120 Sipuleucel-T (Provenge)	Commercial, Medicaid	2Q 2022 annual review: added requirement that "member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy" per NCCN and alignment with other prostate cancer clinical policies; added clarification on approval duration for up to a total of 3 doses; references reviewed and updated.
CP.PHAR.127 Encorafenib (Braftovi)	Commercial, HIM, Medicaid	2Q 2022 annual review: for melanoma, added option for Braftovi monotherapy in melanoma if Mektovi is contraindicated and adjuvant therapy category 2A indication per NCCN; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.176 Paclitaxel protein-bound (Abraxane)	Commercial, HIM, Medicaid	2Q 2022 annual review: removed criterion for Abraxane+Tecentriq combination therapy in triple-negative breast cancer as this indication was withdrawn in August 2021 and no longer supported by NCCN; per NCCN, added "unresponsive to preoperative systemic therapy" as a breast cancer status, added gallbladder cancer indication, added single-agent therapy criterion for

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		cutaneous melanoma, uveal melanoma, and endometrial carcinoma indications, removed bladder cancer indication as this is no longer supported; references reviewed and updated.
CP.PHAR.184 Aflibercept (Eylea)	Commercial, HIM, Medicaid	Added legacy WellCare line of business (WCG.CP.PHAR.184 to be retired) and shortened approval durations from 12 months to 6 months.
CP.PHAR.188 Teriparatide (Forteo)	Commercial, HIM, Medicaid	Per updated prescribing information regarding length of therapy, removed criteria and approval duration requirements that limited therapy to 2 years cumulative PTH analog therapy, added requirement if request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member, added general information regarding fracture risk assessments; added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy; WCG.CP.PHAR.188 retired.
CP.PHAR.228 Trastuzumab Biosimilars Trastuzumab-Hyaluronidase	Commercial, HIM, Medicaid	2Q 2022 annual review: added qualifiers of “advanced” and “recurrent” for gastric, esophageal, or EGJ adenocarcinoma; initial approval durations were consolidated to 6 months for alignment between legacy WCG and other lines of business; removed general description of “stage IV or metastatic” cancer for states with regulations against redirections; clarified other diagnoses section to clarify intent for biosimilar steerage; references reviewed and updated.
CP.PHAR.229 Ado-trastuzumab (Kadcyla)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criterion for single-agent therapy for off-label indications of NSCLC and salivary gland tumor per NCCN; references reviewed and updated.
CP.PHAR.230 AbobotulinumtoxinA (Dysport)	Commercial, HIM, Medicaid	2Q 2022 annual review: revised max dose for blepharospasm from 60 units to 120 units per literature review; revised commercial approval duration from "6 months" (or whatever it is now) to the current standard for injectables of "6 months or to member's renewal date, whichever is

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		longer"; removal of the statement "**The treatment of hyperhidrosis is a benefit exclusion for HIM;*" references reviewed and updated.
CP.PHAR.239 Dabrafenib (Tafinlar)	Commercial, HIM, Medicaid	2Q 2022 annual review: Per NCCN added "limited resectable" melanoma classification, added allowance for therapy without Tafinlar for NSCLC, clarified thyroid cancer should be advanced or metastatic, clarified specific BRAF V600E mutation is a criterion for only ATC of thyroid cancers, added radioactive iodine therapy criterion for follicular, papillary, and Hürthle cell carcinomas, and added indications of central nervous system cancers, hepatobiliary cancers, and histiocytic neoplasms; Commercial approval duration revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.240 Trametinib (Mekinist)	Commercial, HIM, Medicaid	2Q 2022 annual review: added "limited resectable" melanoma classification per NCCN; added indications of central nervous system cancers, hepatobiliary cancers, and histiocytic neoplasms per NCCN; Commercial approval duration revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.246 Canakinumab (Ilaris)	Commercial, HIM, Medicaid	2Q 2022 annual review: applied legacy Wellcare Medicaid line of business; WCG.CP.PHAR.246 to be retired; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.
CP.PHAR.254 Infliximab (Avsola, Inflectra, Remicade, Renflexis)	Medicaid	2Q 2022 annual review: for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; added off-label use for Kawasaki disease; removed unspecified iridocyclitis (ICD10 H20.9) from Section III; applied legacy Wellcare Medicaid (WCG.CP.PHAR.254 to be retired); revised redirection language to biosimilars to "must use" to clarify intent; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.

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CP.PHAR.258 Mitoxantrone (Novantrone)	Commercial, HIM, Medicaid	2Q 2022 annual review: removed references to the brand product Novantrone as it is no longer on market; removed mantle cell lymphoma as a coverable B-cell lymphoma and clarified coverable ALL types per NCCN; clarified interferon-beta product redirections for each line of business per SDC; references reviewed and updated.
CP.PHAR.260 Rituximab (Rituxan, Riabni, Ruxience, Truxima, Rituxan Hycela)	Commercial, HIM, Medicaid	2Q 2022 annual review: clarified GVHD use as steroid-refractory; added NCCN-recommended off-label use for Rosai-Dofrman disease; RT4: updated existing off-label pediatric mature B-Cell NHL criteria to reflect FDA-approved status; removed general description of "stage IV or metastatic" cancer for states with regulations against redirections; clarified other diagnoses/indications section to enforce biosimilar redirection intent; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.
CP.PHAR.264 Ustekinumab (Stelara)	Medicaid	2Q 2022 annual review: for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.
CP.PHAR.265 Vedolizumab (Entyvio)	Medicaid	2Q 2022 annual review: reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.
CP.PHAR.266 Rilonacept (Arcalyst)	Commercial, HIM, Medicaid	2Q 2022 annual review: reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.
CP.PHAR.272 Sonidegib (Odomzo)	Commercial, HIM, Medicaid	2Q 2022 annual review: expanded BCC indication to include local recurrence and added indication of diffuse basal cell carcinoma (BCC) formation per NCCN; added generic redirection criteria; Commercial approval duration revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.273 Vismodegib (Erivedge)	Commercial, HIM, Medicaid	2Q 2022 annual review: added indication of diffuse basal cell carcinoma (BCC) formation per NCCN category 2A recommendation; added generic redirection criteria; WCG.CP.PHAR.273

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		was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.298 Afatinib (Gilotrif)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criteria for single-agent therapy and combination therapy with Erbitux per NCCN; WCG.CP.PHAR.298 was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.316 Cabazitaxel (Jevtana)	HIM, Medicaid	2Q 2022 annual review: added requirement that "member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy" per NCCN and alignment with other prostate cancer clinical policies; removed pregnancy from contraindications per prescribing information; RT4: added new 60 mg/3 mL strength to product availability; references reviewed and updated.
CP.PHAR.319 Ipilimumab (Yervoy)	Commercial, HIM, Medicaid	2Q 2022 annual review: revisions made per NCCN – for melanoma, added pathway for use as a single agent or in combination with Keytruda or Imlygic; for HCC, added additional optional for prior use of Tecentriq + bevacizumab; for NSCLC, removed use in disease positive for tumor mutation burden biomarker, revised requirement for "progression on PD-1/PD-L1 inhibitors" to "no contraindications to PD-1/PD-L1 inhibitors", clarified criteria regarding disease mutation status (unknown status is no longer allowed, and prior targeted therapy is now only required for ROS1 and EGFR S768I, L861Q, and/or G719X mutations), and removed requirement for PD-L1 ≥ 1% as it is not necessary given allowable compendial uses; for uveal melanoma, added requirement that disease is metastatic; updated Appendix D to reflect NCCN's stance on SCLC and TMB NSCLC; references reviewed and updated.
CP.PHAR.335 Ocrelizumab (Ocrevus)	Commercial, HIM, Medicaid	2Q 2022 annual review: added rheumatoid arthritis and lupus nephritis/systemic lupus erythematosus as diagnoses not covered due to safety concerns resulting in termination of the

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		respective clinical studies; added legacy WellCare line of business (WCG.CP.PHAR.335 to be retired); added Coding Implications section; references reviewed and updated.
CP.PHAR.339 Durvalumab (Imfinzi)	Commercial, HIM, Medicaid	2Q 2022 annual review: per prescribing information, for continued therapy, added the following requirement to reemphasize the NSCLC approval duration: "For NSCLC requests, member has not received more than 12 months of Imfinzi therapy"; updated HCPCS code; references reviewed and updated.
CP.PHAR.342 Brigatinib (Alunbrig)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC and IMT indications per NCCN; WCG.CP.PHAR.342 was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.344 Midostaurin (Rydapt)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; WCG.CP.PHAR.344 to be retired and approval durations consolidated to 6 months initial and 12 months for continuation of therapy; per NCCN in AML added option for post-induction therapy prescribed in combination with cytarabine, for myeloid/lymphoid neoplasm added option for use in the chronic phase; references reviewed and updated.
CP.PHAR.349 Ceritinib (Zykadia)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criterion for Zykadia being prescribed as single-agent therapy for NSCLC and inflammatory myofibroblastic tumor indications per NCCN; WCG.CP.PHAR.349 was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.369 Alectinib (Alecensa)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC; added off-label indication criteria for ALCL per NCCN; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.

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CP.PHAR.380 Cobimetinib (Cotellic)	Commercial, HIM, Medicaid	2Q 2022 annual review: added NCCN-supported indications criteria for histiocytic neoplasms and central nervous system cancers; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.385 Corticosteroids for ophthalmic injection (Iluvien, Ozurdex, Retisert, Xipere, Yutiq)	Commercial, HIM, Medicaid	Added legacy WellCare line of business (WCG.CP.PHAR.385 to be retired).
CP.PHAR.406 Lorlatinib (Lorbrena)	Commercial, HIM, Medicaid	2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.416 Caplacizumab-yhdp (Cablivi)	Commercial, HIM, Medicaid	2Q 2022 annual review: for treatment extension requests, added requirement that member continues to have signs of persistent underlying disease per PI; clarified that requirement for maximum 58 days of therapy per treatment cycle applies to treatment extension requests; added Coding Implications section; references reviewed and updated.
CP.PHAR.418 Dexrazoxane (Zinecard Totect)	Commercial, HIM, Medicaid	2Q 2022 annual review: per NCCN added off-label supported uses in patients under 18 years of age in Ph-negative ALL, aggressive mature B-cell lymphomas, Hodgkin lymphoma, or Wilms Tumor (nephroblastoma); removed appendix D that provided references to studies with inconclusive doxorubicin thresholds for use in pediatric patients as such use is supported by NCCN; references reviewed and updated.
CP.PHAR.428 Romosozumab-aqqg (Evenity)	Commercial, HIM, Medicaid	Added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy.
CP.PHAR.447 Mercaptopurine (Purixan)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; modified redirection language from "medical justification" to "member must use"; references reviewed and updated.

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CP.PHAR.468 Aducanumab (Aduhelm)	Commercial, HIM, Medicaid	Revised policy to state Aduhelm is not medically necessary based on current available evidence.
CP.PHAR.475 Sacituzumab govitecan-hziy (Trodelvy)	Commercial, HIM, Medicaid	2Q 2022 annual review: for TNBC: removed "locally advanced" requirement as disease can be local or regional per NCCN; added recurrent urothelial carcinoma indication per NCCN; added criterion for use as single-agent therapy for both TNBC and urothelial cancer per NCCN; references reviewed and updated.
CP.PHAR.478 Selpercatinib (Retevmo)	Commercial, HIM, Medicaid	2Q 2022 annual review: per NCCN added the following: added criterion for use as single-agent therapy for NSCLC and thyroid cancers, added qualifier of recurrent thyroid cancer, removed radioactive iodine criteria for ATC, and added indication criteria for histiocytic neoplasms; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.479 Decitabine-Cedazuridine (Inqovi)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; for decitabine redirection added by-passing of redirection if state regulations do not allow step therapy in certain oncology settings; references reviewed and updated.
CP.PHAR.483 Lisocabtagene maraleucel (Breyanzi)	Commercial, HIM, Medicaid	2Q 2022 annual review: per NCCN added additional AIDS-related uses in diffuse large B-cell lymphoma and HHV8-positive diffuse large B-cell lymphoma; updated HCPCS codes; references reviewed and updated.
CP.PHAR.514 Pralsetinib (Gavreto)	Commercial, Medicaid	2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC; added criterion for DTC that disease is not amenable to radioactive iodine therapy per NCCN; added oral oncology generic redirection language; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated

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CP.PHAR.520 Casirivimab and imdevimab (REGEN-COV)	Commercial, HIM, Medicaid	2Q 2022 annual review: for post-exposure prophylaxis, added a requirement for documentation that the member is at high risk for disease progression and that the member does not have any limitations against use, per the EUA label; RT4: criteria added to reflect new FDA limitation of use against use in regions where infection or exposure is likely due to a non-susceptible SARS-CoV-2 variant; references reviewed and updated.
CP.PHAR.526 Fibrinogen concentrate (human) (Fibryga, RiaSTAP)	Commercial, HIM, Medicaid	2Q 2022 annual review: updated RiaSTAP indication to align with FDA-approved language clarifying use in pediatric patients; clarified requirement for documentation of fibrinogen level and prolonged prothrombin time and activated partial thromboplastin time only applies to new starts on Fibryga/Riastap therapy; references reviewed and updated.
CP.PHAR.528 Odevixibat (Bylvay)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified rifampicin references to rifampin as there are no rifampicin products currently marketed; references reviewed and updated.
CP.PHAR.529 Relugolix (Orgovyx), relugolix-estradiol-norethindrone (Myfembree)	Commercial, HIM, Medicaid	2Q 2022 annual review: for prostate cancer added generic oral oncology redirection if available per template; for heavy menstrual bleeding continuation of therapy added requirement that member has not received ≥ 24 months of Myfembree therapy to reemphasize existing notations for approval duration; references reviewed and updated.
CP.PHAR.530 Tepotinib (Tepmetko)	Commercial, HIM, Medicaid	2Q 2022 annual review: added indication of high-level *MET* amplification in NSCLC per NCCN category 2A; added qualifier for recurrent NSCLC; removed criteria for EGFR wild-type and ALK negative statuses and exclusion for CNS metastases neither NCCN nor the FDA labeling support this restriction; added generic redirection criterion; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PHAR.531 Umbralisib (Ukoniq)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; added generic redirection if available per template for oral oncology products; references reviewed and updated.

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CP.PHAR.532 Bamlanivimab-etesevimab (LY-CoV555-LY-CoV016)	Commercial, HIM, Medicaid	2Q 2022 annual review: added requirement for documentation that this product is not being used for pre-exposure prophylaxis; RT4: criteria added to reflect new FDA limitation of use against use in regions where infection or exposure is likely due to a non-susceptible SARS-CoV-2 variant; references reviewed and updated
CP.PHAR.535 Melphalan flufenamide (Pepaxto)	Commercial, HIM, Medicaid	2Q 2022 annual review: updated HCPCS code; for consistency per label added requirement from initial authorization to continuation of therapy requiring that Pepaxto is prescribed in combination with dexamethasone; references reviewed and updated.
CP.PHAR.538 Tivozanib (Fotivda)	Commercial, HIM, Medicaid	2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; references reviewed and updated.
CP.PMN.193 Hydroxyurea (Siklos)	Commercial, HIM, Medicaid	2Q 2022 annual review: Langerhans Cell Histiocytosis added as option for off-label oncology indication per NCCN-supported category 2A recommendation; references reviewed and updated.
CP.PMN.262 Quinine Sulfate (Qualaquin)	Commercial, HIM, Medicaid	2Q 2022 annual review: for babesiosis, added requirement for use in combination with clindamycin per IDSA and CDC; references reviewed and updated.
CP.PMN.264 Viloxazine (Qelbree)	Commercial, HIM, Medicaid	2Q 2022 annual review: HIM line of business added; references reviewed and updated.
New		
CP.PHAR.575 Tebentafusp-tebn (Kimmtrak)	Commercial, HIM, Medicaid	Policy created.
CP.PHAR.576 Tezepelumab (Tezspire)	Commercial, HIM, Medicaid	Policy created.
CP.PHAR.577 Tralokinumab-ldrm (Adbry)	Commercial, HIM, Medicaid	Policy created.

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CP.PMN.275 Levoketoconazole (Recorlev)	Commercial, HIM, Medicaid	Policy created.
CP.PMN.276 Pentosan polysulfate sodium (Elmiron)	Commercial, Medicaid	Policy created.
CP.PMN.277 Ulcer Therapy Combinations (Omeclamox Pak, Pylera, Talicia)	Commercial, HIM, Medicaid	Policy created.
No Significant Change(s)		
CP.PHAR.16 Palivizumab (Synagis)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; Appendix D updated to include American Academy of Pediatrics (AAP) updated guidance for the 2021-2022 RSV season; references reviewed and updated.
CP.PHAR.43 Sapropterin (Kuvan)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.88 Belimumab (Benlysta)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.152 Laronidase (Aldurazyme)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of member's current weight for dose calculation purposes; references reviewed and updated.
CP.PHAR.153 Eliglustat (Cerdelga)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.154 Imiglucerase (Cerezyme)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of member's current weight for dose calculation purposes; added max dosing recommendations per Prescribing Information; references reviewed and updated.

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CP.PHAR.155 Cysteamine oral (Cystagon, Procysbi)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; WCG.CP.PHAR.155 retired and approval durations consolidated to 6 month initial and 12 months for continued therapy; references reviewed and updated.
CP.PHAR.156 Idursulfase (Elaprase)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of member's current weight for dose calculation purposes; referenced reviewed and updated.
CP.PHAR.157 Taliglucerase alfa (Elelyso)	Commercial, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of member's current weight for dose calculation purposes; added max dosing recommendations per Prescribing Information; references reviewed and updated.
CP.PHAR.158 Agalsidase beta (Fabrazyme)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.159 Sebelipase alfa (Kanuma)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of member's current weight for dose calculation purposes; updated max recommended dose for members with rapidly progressive disease presenting within the first 6 months of life per the Prescribing Information and clarified documentation requirements for max dose requests for this population; references reviewed and updated.
CP.PHAR.160 Alglucosidase (Lumizyme)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement that Lumizyme not be prescribed concurrently with Nexviazyme; references reviewed and updated.
CP.PHAR.161 Galsulfase (Naglazyme)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of member's current weight for dose calculation purposes; references reviewed and updated.
CP.PHAR.162 Elosulfase alfa (Vimizim)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added requirement for documentation of current weight for dose calculation purposes; references reviewed and updated.
CP.PHAR.163 Velaglucerase alfa (VPRIV)	Commercial, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.

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CP.PHAR.164 Miglustat (Zavesca)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; removed the requirement for mild to moderate GD1 severity for coverage based on subjectivity of defining disease severity; references reviewed and updated.
CP.PHAR.227 Pertuzumab (Perjeta)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.
CP.PHAR.231 IncobotulinumtoxinA (Xeomin)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; removal of the statement "**The treatment of hyperhidrosis is a benefit exclusion for HIM;"* revised commercial approval duration from "6 months" (or whatever it is now) to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; references reviewed and updated.
CP.PHAR.232 OnabotulinumtoxinA (Botox)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; WCG.CP.PHAR.232 policy retired per SDC recommendation; removal of required 2 week trial duration of nitroglycerin and nifedipine/diltiazem for chronic anal fissures; adjusted Xeomin blepharospasm dose in Appendix B from 25 units to 50 units per PI; removal of the statement "**The treatment of hyperhidrosis is a benefit exclusion for HIM;*" references reviewed and updated.
CP.PHAR.233 RimabotulinumtoxinB (Myobloc)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; revised Commercial approval duration from "6 months" (or whatever it is now) to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; removed in Section III "Ambetter, hyperhidrosis is a benefit exclusion categorized as a cosmetic service"; references reviewed and updated.
CP.PHAR.243 Alemtuzumab (Lemtrada)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; clarified interferon-beta product redirections for each line of business per SDC; references reviewed and updated.
CP.PHAR.259 Natalizumab (Tysabri)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added Commercial and HIM lines of business (CP.CPA.82 and HIM.PA.SP17 to be retired); references reviewed and updated.
CP.PHAR.294 Osimertinib (Tagrisso)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.

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CP.PHAR.306 Ofatumumab (Arzerra, Kesimpta)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; clarified B-cell lymphoma criteria per NCCN recommendations; clarified interferon-beta product redirections for each line of business per SDC; references reviewed and updated.
CP.PHAR.337 Telotristat ethyl (Xermelo)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.343 Edaravone (Radicava)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.374 Vestronidase alfa-vjbk (Mepsevii)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.376 Apalutamide (Erleada)	Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.378 Ibalizumab-uiyk (Trogarzo)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.417 Brexanolone (Zulresso)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.419 Elapegademase-lvlr (Revcovi)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.421 Onasemnogene abeparvovec (Zolgensma)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.462 Ozanimod (Zeposia)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.469 Belantamab mafodotin (Blenrep)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; updated HCPCS codes; references reviewed and updated.
CP.PHAR.471 Fosdenopterin (Nulibry)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.

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CP.PHAR.474 Remestemcel-L (Ryoncil)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.480 Ferric Derisomaltose (Monoferric)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.481 Idecabtagene vicleucel (Abecma)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; updated HCPCS codes; references reviewed and updated.
CP.PHAR.482 Isatuximab-irfc (Sarclisa)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.486 Bimatoprost Implant (Durysta)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.504 Voclosporin (Lupkynis)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.521 Avalglucosidase alfa-ngpt (Nexviazyme)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.527 Narsoplimab (OMS721)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes as drug is not yet FDA-approved; references reviewed and updated.
CP.PHAR.533 Ciltacabtagene Autoleucel	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.536 Ophthalmic Riboflavin (Photrexa, Photrexa Viscous)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PHAR.537 Ponesimod (Ponvory)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; clarified interferon-beta product redirections for each line of business per SDC; references reviewed and updated.
CP.PMN.35 Armodafinil (Nuvigil)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.

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CP.PMN.39 Modafinil (Provigil)	HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.58 Propranolol (Hemangeol)	HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.61 ACEI and ARB duplicate therapy	Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.86 Oxymetazoline (Rhofade, Upneeq)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; added 60 g tube and 30 and 60 g pump formulations of Rhofade; references reviewed and updated.
CP.PMN.118 Netarsudil (Rhopressa), Netarsudil-Latanoprost (Rocklatan)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.119 Ozenoxacin (Xepi)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.126 Toremifene (Fareston)	Medicaid	2Q 2022 annual review: no significant changes; Appendix D information added re toremifene no longer being NCCN-supported in breast cancer; references reviewed and updated.
CP.PMN.130 Cysteamine ophthalmic (Cystaran, Cystadrops)	Commercial*, HIM*, Medicaid	2Q 2022 annual review: no significant changes; added legacy WellCare and shortened initial approval duration from 12 months to 6 months (WCG.CP.PMN.130 to be retired); added note referring reviewers to the HIM/Commercial formulary exception policies for Cystadrops requests given its NF status; references reviewed and updated.
CP.PMN.136 Mecamylamine (Vecamyl)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.137 Carbamazepine ER (Equetro)	Commercial, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.138 Age Limit Override (Codeine, Tramadol, Hydrocodone)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.192 Brimonidine (Mirvaso)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.

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CP.PMN.196 Rifamycin (Aemcolo)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.199 Esketamine (Spravato)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.209 Solriamfetol (Sunosi)	Commercial, HIM, Medicaid	2Q 2022 annual review: no significant changes; references reviewed and updated.
CP.PMN.234 EPSDT Benefit for Pediatric Members	Medicaid	2Q 2022 annual review: no significant changes; added legacy WellCare line of business (WCG.CP.PMN.234 to be retired) with initial approval duration consolidated to 6 months; references reviewed and updated.
Strategy Development Committee (SDC) Criteria changes based on SDC decisions		
CP.PHAR.97 Eculizumab (Soliris)	Commercial, HIM, Medicaid	Per February SDC and prior clinical guidance, for NMOSD added stepwise redirection requirement if member has failed rituximab, then member must use Enspryng.
CP.PHAR.458 Inebilizumab-cdon (Uplizna)	Commercial, HIM, Medicaid	Per February SDC and prior clinical guidance, added stepwise redirection requirement if member has failed rituximab, then member must use Enspryng.
CP.PMN.223 Rifabutin (Mycobutin)	HIM, Medicaid	Per February SDC and prior clinical guidance, removed Talicia from policy (new policy created for ulcer therapy combinations).

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