

NH Healthy Families Pharmacy & Therapeutics Committee 4Q19

Coverage Criteria Guideline	Revision Summary Description
CP.PHAR.65 Imatinib (Gleevec)	PVNS/TGCT: added requirement that disease is not amenable to improvement with surgery to align with Turalio since both drugs have the same recommendations for use per NCCN.
CP.PHAR.79 Lapatinib (Tykerb)	4Q 2019 annual review: added bone cancer off-label use criteria per NCCN 2A recommendation; references reviewed and updated.
CP.PHAR.93 Bevacizumab (Avastin, Mvasi, Zirabev)	4Q 2019 annual review: added NCCN category 2A recommended off-label uses: meningioma, small bowel adenocarcinoma; references reviewed and updated.
CP.PHAR.97 Eculizumab (Soliris)	Criteria added for new FDA indication: neuromyelitis optica spectrum disorder; references reviewed and updated.
CP.PHAR.98 Ruxolitinib (Jakafi)	Criteria added for new FDA indication: steroid-refractory acute graft-versus-host disease; references reviewed and updated.
CP.PHAR.129 Venetoclax (Venclexta)	4Q 2019 annual review: CLL/SLL monotherapy or combination therapy with rituximab added in the subsequent therapy setting; AML NCCN alternative uses for relapse/refractory disease and remission added; Appendix B updated to reconcile with similar policies; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.130 Avatrombopag (Doptelet)	4Q 2019 annual review: criteria added for new FDA indication: chronic immune thrombocytopenia; references reviewed and updated.
CP.PHAR.133 Idelalisib (Zydelig)	4Q 2019 annual review: Criteria/Appendix B reorganized to reconcile with similar policies; FDA/NCCN dosing limitation added, references reviewed and updated.
CP.PHAR.137 Ivosidenib (Tibsovo)	4Q 2019 annual review: FDA/NCCN dosing limitation added; induction therapy examples for patients over 60 added; references updated.
CP.PHAR.138 Lenvatinib (Lenvima)	4Q 2019 annual review: NCCN designation of recurrent added to MTC criteria; references reviewed and updated.
CP.PHAR.169 Vigabatrin (Sabril)	For Refractory Complex Partial Seizures (CPS): Modified failure of two preferred alternative anticonvulsant drugs to a failure of three agents; references reviewed and updated.
CP.PHAR.170 Degarelix (Firmagon)	4Q 2019 annual review: for prostate cancer added urologist specialist option; references reviewed and updated.
CP.PHAR.171 Goserelin Acetate (Zoladex)	4Q 2019 annual review: removed pregnancy safety requirement for breast cancer and endometriosis indications; added oncologist prescriber requirement for breast cancer; for prostate cancer removed requirement for use of 3.6 mg or 10.8 mg strengths as those are the only available strengths, added urologist specialist option; for dysfunctional uterine bleeding added requirement to Section I and II to validate member has not yet received two implants; references reviewed and updated.
CP.PHAR.184 Aflibercept (Eylea)	Criteria added for new FDA indication: use in patients with diabetic retinopathy without diabetic macular edema; references updated.
CP.PHAR.231 IncobotulinumtoxinA (Xeomin)	Criteria updated for new FDA approved indication: first-line treatment for blepharospasms; references reviewed and updated.
CP.PHAR.245 Apremilast (Otezla)	Criteria added for new FDA indication: treatment of adult patients with oral ulcers associated with Behçet's disease; references updated.
CP.PHAR.260 Rituximab (Rituxan, Truxima, Rituxan Hycela)	Criteria added for off-label use in neuromyelitis optica spectrum disorder; references reviewed and updated.
CP.PHAR.305 Obinutuzumab (Gazyva)	4Q 2019 annual review: NCCN recommended uses added for B-cell lymphomas; FDA/NCCN dosing limitation added, references updated.
CP.PHAR.306 Ofatumumab (Arzerra)	4Q 2019 annual review: NCCN recommendations for B-cell lymphomas added; FDA/NCCN dosing limitation added; 12 doses added as maximum per PI for refractory CLL; Arzerra use in WM/LPL restated as second-line or subsequent therapy; references reviewed and updated.
CP.PHAR.307 Bendamustine (Bendeka, Treanda)	4Q 2019 annual review: added additional therapeutic alternatives to Appendix B with NCCN category 1: MM; added hepatosplenic gamma-delta T-cell lymphoma to non-Hodgkin T-cell lymphomas (off-label) uses and related therapeutic alternatives to Appendix B; references reviewed and updated.
CP.PHAR.308 Elotuzumab (Empliciti)	4Q 2019 annual review: FDA/NCCN dosing requirement added; references reviewed and updated.
CP.PHAR.309 Carfilzomib (Kyprolis)	4Q 2019 annual review: Kyprolis with dexamethasone only dosing updated; references reviewed and updated.
CP.PHAR.311 Belinostat (Beleodaq)	4Q 2019 annual review: added NCCN-recommended (with Category 2A or above) off-label uses: extranodal NK/T-cell lymphoma, nasal type, hepatosplenic gamma-delta T-cell lymphoma; references reviewed and updated.
CP.PHAR.313 Pralatrexate (Folotylin)	4Q 2019 annual review: FDA/NCCN dosing requirement added; failed prior therapy added for PTCL; off-label uses added with prior therapy (HGTL, NKTL); prior therapy added for ATLL; references reviewed and updated.
CP.PHAR.314 Romidepsin (Istodax)	4Q 2019 annual review: FDA dosing cycle details added; FDA/NCCN labeling requirement added; references reviewed and updated.

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CP.PHAR.315 Vincristine Liposome (Marqibo)	4Q 2019 annual review: Ph- anti-leukemia therapy examples added to Appendix B; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.321 Panitumumab (Vectibix)	4Q 2019 annual review: references reviewed and updated.
CP.PHAR.322 Pembrolizumab (Keytruda)	4Q 2019 annual review: criteria added for new FDA indication for esophageal squamous cell carcinoma; added chondrosarcomas as another example of an NCCN-supported MSI-H/dMMR tumor type in <i>Appendix D</i> ; references reviewed and updated.
CP.PHAR.324 Temsirolimus (Torisel)	4Q 2019 annual review: updated NCCN dosing per new template; added RCC prognostic risk factors; references reviewed and updated.
CP.PHAR.325 Ziv-aflibercept (Zaltrap)	4Q 2019 annual review: references reviewed and updated.
CP.PHAR.332 Pasireotide (Signifor, Signifor LAR)	4Q 2019 annual review: increased acromegaly initial approval duration from 3 months to 6 months to align with approach for other acromegaly policies; references reviewed and updated.
CP.PHAR.336 Dupilumab (Dupixent)	Criteria added for new FDA indication: CRSwNP; added allergists as potential prescribers for atopic dermatitis; references updated.
CP.PHAR.352 Daunorubicin-cytarabine (Vyxeos)	4Q 2019 annual review: antecedent MDS/CMML added per NCCN; cycle details added per PI; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.353 Pegaspargase (Oncaspar)	4Q 2019 annual review: ALL age limit/drug trial removed per PI; off-label T-cell age limit added in absence of NCCN pediatric guidance; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.354 Testosterone (Testopel)	4Q 2019 annual review: added therapeutic alternatives to <i>Appendix B</i> ; added age-related hypogonadism or late-onset hypogonadism to Section III for excluded diagnoses; references reviewed and updated.
CP.PHAR.357 Copanlisib (Aliqopa)	4Q 2019 annual review: NCCN recommended B-cell lymphoma subtypes added - Appendix B required therapy examples expanded accordingly; relapsed or refractory disease added; dosing detail - 3 out of 4 weeks - added per PI; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.358 Gemtuzumab (Mylotarg)	4Q 2019 annual review: FDA/NCCN dosage limitations added; references reviewed and updated.
CP.PHAR.359 Inotuzumab Ozogamicin (Besponsa)	4Q 2019 annual review: FDA/NCCN dosing limitation added; age removed to encompass pediatrics per NCCN; references updated.
CP.PHAR.361 Tisagenlecleucel (Kymriah)	ALL: per NCCN treatment guidelines and clinical trial inclusion criteria modified previous therapy requirement to require one of the following (a, b, or c): a) Disease is refractory or member has had ≥ 2 relapses; b) Disease is Philadelphia chromosome positive: failure of 2 lines of chemotherapy that included 2 tyrosine kinase inhibitors; c) Member has relapsed following HSCT and must be ≥ 6 months from HSCT at the time of Kymriah infusion; references reviewed and updated.
CP.PHAR.363 Enasidenib (Idhifa)	4Q 2019 annual review: NCCN use added - relapse/remission post Idhifa therapy; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.387 Azacitidine (Vidaza)	4Q 2019 annual review: MDS – added options for use as bridge therapy while awaiting HSCT donor availability or in patients with clinically relevant thrombocytopenia/neutropenia or increased bone marrow blasts per NCCN; AML for members ≥ 60 years – added combination use with Nexavar and Venclexta and simplified uses as Vidaza can be used for both induction and maintenance therapy in elderly patients declining more aggressive therapy per NCCN; references reviewed and updated.
CP.PHAR.391 Lanreotide (Somatuline Depot)	4Q 2019 annual review: bronchopulmonary/thymic NETs: simplified I.D.1 to “unresectable or metastatic bronchopulmonary/thymic NET” and modified I.D.4 to only require somatostatin receptor positive imaging and/or hormonal symptoms per NCCN compendium; references reviewed and updated.
CP.PHAR.398 Moxetumomab pasudotox-tdfk (Lumoxiti)	4Q 2019 annual review: cycle details added to FDA dosing; FDA/NCCN dosing limitations added; references reviewed and updated.
CP.PHAR.399 Dacomitinib (Vizimpro)	4Q 2019 annual review: NCCN designation of advanced added; additional examples of sensitizing EGFR mutations added consistent with NCCN; references reviewed and updated.
CP.PHAR.400 Duvelisib (Copiktra)	4Q 2019 annual review: FDA/NCCN dosing limitation added; marginal zone lymphomas added per NCCN; references updated.
CP.PHAR.404 Galcanezumab-gnlm (Emgality)	Criteria added for new FDA approved indication: episodic cluster headaches; added chronic cluster headaches to Section III as a diagnosis not covered; references reviewed and updated.

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NH.PMN.16 Request for non-preferred medically necessary drug	New Policy Created
CP.PMN.47 Rifaximin (Xifaxan)	4Q 2019 annual review: for SIBO added requirement for age 18 or older; references reviewed and updated.
CP.PMN.53 No Coverage Criteria-Off-Label Use	4Q 2019 annual review: added requirement that member does not have any contraindications for labeled use without coverage criteria; references reviewed and updated.
CP.PMN.54 Clobazam (Onfi, Sympazan)	4Q 2019 annual review: added reference to non-formulary policy for Sympazan; reference reviewed and updated.
CP.PMN.109 Suvorexant (Belsomra)	4Q 2019 annual review: removed 14-day trial duration requirement to align with other insomnia policies; references reviewed and updated.
CP.PMN.170 Eluxadoline (Viberzi)	4Q 2019 annual review: references reviewed and updated.
CP.PMN.172 Zolpidem (Edluar, Intermezzo, Zolpimist)	4Q 2019 annual review: increased initial approval duration for Medicaid to 6 months to align with approach for other sleep agents; clarified zolpidem redirection for Edluar and Zolpimist is to the oral tablet formulation; references reviewed and updated.
CP.PMN.175 Doxepin (Silenor)	4Q 2019 annual review: added option for previous history of substance abuse to bypass requirement for trial of zolpidem; references reviewed and updated.
CP.PMN.184 Stiripentol (Diacomit)	4Q 2019 annual review: added requirement that Diacomit continue to be used as adjunctive therapy for reauthorization; references reviewed and updated.
CP.PHAR.435 Darolutamide (Nubeqa)	Policy created.
CP.PHAR.436 Pexidartinib (Turalio)	Policy created.
CP.PHAR.437 Thioguanine (Tabloid)	Policy created; AML relabeled as “myeloid” and ALL age limited to pediatrics per NCCN guidelines; mercaptopurine trial removed from AML given the drug’s lack of FDA label and from ALL given the new pediatric age restriction; FDA/NCCN dosing limitation added; references reviewed and updated.
CP.PHAR.438 Trientine (Syprine)	Policy created.
CP.PHAR.439 Valrubicin (Valstar)	Policy created.
CP.PMN.212 Bedaquiline (Sirturo)	Policy created; added additional therapy options to Appendix B (alphabetized table) based on 2019 WHO guidelines and commercially available in the US (ethambutol, imipenem-cilastatin, linezolid, meropenem); updated FDA-approved age limit to 12 years of age and older; references reviewed and updated.
CP.PMN.213 Ferric maltol (Accrufer)	Policy created.
CP.PMN.214 Continuous Glucose Monitors	Policy created.
CP.PMN.215 Non-preferred blood glucose monitors and test strips	Policy created.
CP.PHAR.27 Tolvaptan (Jynarque, Samsca)	4Q 2019 annual review: no significant changes; added to contraindications and boxed warnings per updated prescribing information; references reviewed and updated.
CP.PHAR.125 Palbociclib (Ibrance)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.128 Erenumab-aaoe (Aimovig)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.132 Nitisinone (Nityr, Orfadin)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.134 Methotrexate (Otrexup, Rasuvo, Xatmep)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.136 Elagolix (Orilissa)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.139 Mogamulizumab-kpkc (Poteligeo)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.140 Pegvaliase-pqz (Palynziq)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.141 Ribavirin (Copegus, Moderiba, Rebetol, Ribasphere)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.142 Adefovir (Hepsera)	4Q 2019 annual review: no significant changes; references reviewed and updated.

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CP.PHAR.143 Betaine (Cystadane)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.149 Intrathecal Baclofen (Gablofen, Lioresal)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.151 Levoleucovorin (Fusilev)	4Q 2019 annual review: no significant changes; additional cancers amenable to rescue therapy added to Appendix D per NCCN; updated off-label dosing per new template; references reviewed and updated.
CP.PHAR.174 Nafarelin Acetate (Synarel)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.201 Belatacept (Nulojix)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.304 Irinotecan Liposome (Onivyde)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.317 Cetuximab (Erbix)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.318 Eribulin Mesylate (Halaven)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.320 Necitumumab (Portrazza)	4Q 2019 annual review: no significant changes; added general information stating lack of NCCN support for Portrazza based regimen; references reviewed and updated.
CP.PHAR.326 Olaratumab (Lartruvo)	4Q 2019 annual review: no significant changes; updated Appendix D to state NCCN guidelines' removal of doxorubicin and olaratumab as a combination therapy for STS and uterine sarcoma; references reviewed and updated.
CP.PHAR.328 Asfotase Alfa (Strensiq)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.334 Ribociclib (Kisqali), Ribociclib/Letrozole (Kisqali Femara)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.355 Abemaciclib (Verzenio)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.365 Neratinib (Nerlynx)	4Q 2019 annual review: removed off-label capecitabine combination use from criteria (NCCN category 2B); references updated
CP.PHAR.389 Pegvisomant (Somavert)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.390 Cholic Acid (Cholbam)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.392 Pegademase Bovine (Adagen)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.393 Leucovorin Injection	4Q 2019 annual review: no significant changes; additional cancers amenable to rescue therapy added to Appendix D per NCCN; updated off-label dosing per new template; references reviewed and updated.
CP.PHAR.394 Migalastat (Galafold)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.395 Patisiran (Onpattro)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PHAR.397 Cemiplimab-rwlc (Libtayo)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.17 Droxidopa (Northera)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.71 Linaclotide (Linzess)	4Q 2019 annual review: no significant changes from previously approved corporate policy; references reviewed and updated.
CP.PMN.73 Lifitegrast (Xiidra)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.75 Age Limit for Tazarotene (Tazorac)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.87 Plecanatide (Trulance)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.112 Naldemedine (Symproic)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.114 Betrixaban (Bevyxxa)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.116 L-glutamine (Endari)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.142 Lubiprostone (Amitiza)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.143 Isotretinoin (Claravis, Absorica, Myorisan, Zenatane)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.153 Alosetron (Lotronex)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.161 Methadone (Dolophine)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.162 Moxidectin	4Q 2019 annual review: no significant changes; references reviewed and updated.

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CP.PMN.165 Fluorouracil Cream (Tolak)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.167 Neomycin/Fluocinolone Cream (Neo-Synalar)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.169 Methylnaltrexone Bromide (Relistor)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.171 Naloxegol (Movantik)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.173 Ramelteon (Rozerem)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.174 Perindopril-Amlodipine (Prestalia)	4Q 2019 annual review: clarified that medical justification must support inability for <i>concurrent</i> use of individual components; no significant changes; references reviewed and updated.
CP.PMN.177 Glycopyrronium (Qbrexza)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.178 Tafenoquine (Arakoda)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.179 Megestrol Acetate (Megace ES)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.180 Halobetasol Propionate Lotion 0.05% (Ultravate)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.181 Calcipotriene/Betamethasone Dipropionate Foam (Enstilar)	4Q 2019 annual review: revised age limit to 12 years and older per FDA pediatric extension; no significant changes; references updated.
CP.PMN.182 Betamethasone Dipropionate Spray (Sernivo)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.185 Baloxavir Marboxil (Xofluza)	4Q 2019 annual review: no significant changes; references reviewed and updated.
CP.PMN.210 Acyclovir Buccal Tablet (Sitavig), Ophthalmic Ointment (Avaclyr)	4Q 2019 annual review: no significant changes; references reviewed and updated.

Coverage Criteria Guideline	Revision Summary Description
CC.PHAR.06 PBM Inquiry for Additional Information	Review against current NCQA standards and guidelines and revision of the Procedure section, based on current process and requirements. Response to Prior Authorization Medication Request Form Attachment retired and removed.
NH.PHAR.09 Pharmacy Program	Safety Issues section- Removed “pharmacy providers” from notifications, added Class II and III alerts to health plan notifications, removed “When a high level of concern for safety is identified” as a prerequisite for when Envolve supplies the health plan with a list of affected members and providers, added providers to health plan’s responsibility for notifications, removed “Class II and III alerts are evaluated according to their potential to cause harm and generally pose minimal risks to a patient’s health, but may be acted on if judged appropriate”.
CC.PHAR.11 Requests for Pharmacy Profiles	Annual Review- No changes deemed necessary.
NH.PHAR.14 Pharmacy Lock-In Program	Minor grammatical changes, added safety of the member element under purpose, added cause for multiple pharmacies element, adding extenuating circumstances for change in lock-in pharmacy. Changed quarter to period. Reduced 4 physicians and pharmacies down to 3. Added in patient’s right to select pharmacy within 21 days of notice. Added that member lock in status would be pended during an active appeal.
NH.PHAR.20 Medication Therapy Management Program	Policy created
NH.PHAR.135 Drug Utilization Review	Added Polypharmacy section, minor grammatical changes