CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 CLINICAL POLICY (BIOPHARM SPECIALTY) SUMMARY

Coverage Guideline Policy & Procedure	Status	Revision Summary or Description
NH.PHAR.125 Omalizumab	Reviewed	Annual Review, No Changes
CP.PHAR.74 Erlotinib	Revised	Language for NSCLC maintenance therapy changed to "maintenance therapy for metastatic disease after prior chemotherapy". Maintenance therapy is deleted from the NSCLC NCCN recommended use. Vulvar cancer is added as an additional recommended use. Under section II. Continued Approval, the following edits are made to reasons to discontinue: 1) Added "If pre-existing hepatic impairment or biliary obstruction, a doubling of bilirubin or tripling of transaminase (ALT/AST) values over baseline that does not improve significantly or resolve within 3 weeks"; 2) removed "no disease progression or unacceptable toxicities."
CP.PHAR.81 Pazopanib	Revised	Converted policy to new template. Removed prescriber and age requirements per template guidelines. In initial criteria, removed exclusions based on medical conditions if they were presented in the PI as discontinuation recommendations (they are maintained under continuation criteria). Added NCCN recommended uses.
CP.PHAR.82 Collagenase Clostridium Histolyticum	Revised	Converted policy to new template. Removed age limitation and added max dose for both indications.
CP.PHAR.83 Vorinostat	Revised	Policy converted to new template. Two appendices added – classification of CTCL and examples of CTCL systemic therapies. NCCN recommended uses added.
CP.PHAR.84 Abiraterone	Revised	Added max dose for concomitant use with a strong CYP3A4 inducer.
CP.PHAR.92 Tetrabenazine	Revised	Policy converted to new template. Age removed; max dose added. Definition of hepatic impairment is added as Child-Pugh A, B or C.
CP.PHAR.103 Immune Globulin	Revised	Early revision to add Cuvitru approved in September, 2016.
CP.PHAR.107 Regorafenib	Revised	Converted policy to new template. Removed prescriber and age requirements. CRC mutations: The RAS family of mutations includes but is not limited to KRAS and NRAS mutations. All mutation designations are represented in the policy per FDA/NCCN language.

		In initial criteria for CRC and GIST, removed exclusions based on medical conditions if they were presented in the PI as discontinuation recommendations; however, they are maintained under continuation criteria. In continuation criteria, edited reasons to discontinue to those that are permanent discontinues. NCCN recommended uses: For CRC, all NCCN recommended uses are added; for GIST the NCCN uses match the FDA approved uses so NCCN is not listed separately.
CP.PHAR.108 Omacetaxine	Revised	Policy converted to new template. Added prescriber and age requirements. Added NCCN recommended use (CML relapse post-transplantation). Removed attestation that member does not have poorly controlled diabetes from initial criteria.
CP.PHAR.120 Sipuleucel-T	Revised	NCCN criteria to support appropriate use (i.e., ECOG 0-1, no hepatic metastases, estimated life expectancy > 6 months).
CP.PHAR.151 Levoleucovorin	Revised	Added contraindication (allergy). Added "responding positively to therapy" under "Methotrexate/Folic Acid Antagonist Toxicity Prophylaxis" continuation criteria. Removed detailed language under CRC continuation criteria regarding whether member has recovered between successive regimens and replaced it with "no disease progression or unacceptable toxicity". NCCN recommended uses added. Added formulations.
CP.PHAR.152 Laronidase	Revised	Age restriction removed. Allergy history removed. Initial approval duration extended to 6 months. Positive response to therapy added. Background section converted to new template.
CP.PHAR.153 Eliglustat	Revised	Age restriction removed. Max dose added. Monotherapy requirement added. Conditions for which Cerdelga is not recommended are added to initial criteria per the PI. Initial approval extended to 6 months for consistency across similar policies. Positive response to therapy added. Background section converted to new template.
CP.PHAR.154 Imiglucerase	Revised	Age restriction removed. Allergy history removed as the drug can be continued in some cases. DNA testing added to diagnostic methods. ERT monotherapy added. Positive response to therapy added. Background section converted to new template.
CP.PHAR.155 Cysteamine	Revised	Age restriction removed. Additional diagnostic criteria added. Reasons to discontinue added to continuation criteria. Positive response to therapy added. Background section converted to new template.
CP.PHAR.156 Idursulfase	Revised	Age restriction removed. Allergy history is removed as the drug can be continued in some cases. Positive response to therapy added. Background section converted to new template.
CP.PHAR.157 Taliglucerase alfa	Revised	Age restriction removed.

		Concomitant use with Zavesca is removed but the Zavesca policy includes a monotherapy requirement. Allergy history is removed as the drug can be continued in some cases. Background section converted to new template.
CP.PHAR.158 Agalsidase beta	Revised	Age restriction removed. Allergy history is removed as the drug can be continued in some cases. Initial approval extended to 6 months for consistency across similar policies. Positive response to therapy added. Background section converted to new template.
CP.PHAR.159 Sebelipase alfa	Revised	A ge restriction removed. Allergy history is removed as the drug can be continued in some cases. Positive response to therapy added. Background section converted to new template.
CP.PHAR.160 Alglucosidase alfa	Revised	Age restriction removed. Positive response to therapy added. Background section converted to new template. Lumizyme PI remains the same; Myozyme is no longer available in the U.S.
CP.PHAR.161 Galsulfase	Revised	Age restriction removed. Allergy history is removed as the drug can be continued in some cases. Positive response to therapy added. Background section converted to new template.
CP.PHAR.162 Elosulfase alfa	Revised	Age restriction removed. Allergy history is removed as the drug can be continued in some cases. Positive response to therapy added. Background section converted to new template. PI remains the same.
CP.PHAR.163 Velaglucerase alfa	Revised	Age restriction removed. DNA testing added to diagnostic methods. Allergy history is removed as the drug can be continued in some cases. ERT monotherapy added. Positive response added. Background section converted to new template.
CP.PHAR.164 Miglustat	Revised	Removed age restriction. DNA testing added to diagnostic methods. Max dose added. Severe renal impairment as a restriction is added to initial and continuation criteria per the PI. Hand tremors added to the continuation criteria per the PI. Positive response to therapy added. Continuation approval period extended to 12 months. Background section converted to new template.
CP.PHAR.169 Vigabatrin	Revised	Infantile spasms: Lower age limit of one month is removed and left to provider discretion; dosing is removed given verification challenges around weight-based dosing; monotherapy is removed since other seizure medications are available without a PA making verification problematic. Complex partial seizures: Adjunctive therapy is defined and examples of anticonvulsant therapies are added per the PI; dosing is added to the continued approval section. Informational footnotes regarding dosing are added to both initial approval sections. Efficacy criteria are added to both continued approval sections. Classification of seizures per ILAE is added at Appendix B. PI black box warning is restated verbatim at Appendix C.

		Periodic visual monitoring is required under the REMS program and so is not stated separately in the criteria; documentation of REMS enrollment also is removed from criteria sets since it is required separately under the REMS program for both members and providers. Classification and guideline/consensus documentation is added to reference section.
CP.PHAR.170 Degarelix acetate	Revised	Age removed. Formulations added. Off-label NCCN recommended uses added (prostate and breast cancer; doses removed).
CP.PHAR.171 Goserelin acetate	Revised	Age removed. Formulations added. Off-label NCCN recommended uses added (prostate and breast cancer; doses removed; 3-month injectable requirement removed).
CP.PHAR.172 Histrelin acetate	Revised	Prostate cancer: Age removed – while safety and effectiveness in pediatric patients has not been established per the PI, the PI stops short of recommending that Vantus not be used in pediatrics. NCCN recommendations added (prostate cancer; doses removed). Formulations added. Added HCPCS Codes for Vantas and Supprelin LA implants
CP.PHAR.173 Leuprolide acetate	Revised	Cancer, endometriosis and pelvic pain, and anemia: age removed - while safety and effectiveness in pediatric patients has not been established per the PIs, the PIs stop short of recommending that leuprolide products not be used in pediatrics. Criteria for endometriosis and pelvic pain is edited to require a trial of both NSAIDs and oral contraceptives. NCCN recommended uses added (prostate cancer; doses removed; breast and ovarian cancer are moved to the “other diagnoses” section per template guidelines). Formulations added.
CP.PHAR.174 Nafarelin acetate	Revised	Endometriosis and pelvic pain: age removed.
CP.PHAR.175 Triptorelin pamoate	Revised	Age removed. Formulations added. NCCN recommended uses added (prostate cancer; doses removed).
CP.PHAR.235 Atezolizumab	Revised	New labeled indication added: Non-small cell lung cancer.
CP.PHAR.246 Canakinumab	Revised	Added criteria for the new FDA-approved indications: TRAPS, HIDS/MKD, and FMF. Made the following changes to the existing criteria: -CAPS: Modified specialist requirement to include physicians experienced in the management of CAPS. Removed age restriction. Added maximum dose criteria. Modified initial approval duration to 12 weeks. -SJIA: Removed age restriction. Added maximum dose criteria per package insert. Modified initial approval duration to 8 weeks. -Re-auth: Added examples of positive response for all indications. Added that continued therapy may be approved despite inadequate response if request is for a dose increase.

		Updated formulation section in background to 150 mg powder (vs 180 mg powder), and modified to be more concise. Updated references.
CP.PHAR.254 Infliximab	Revised	Added preferencing for Inflectra prior to allowing Remicade, except for UC patients aged 6-18. CD: Removed corticosteroid as an option for trial/failure. UC: removed aminosalicylates and corticosteroids as potential acceptable first-line therapies. PsA: Preferenced trial of MTX above other DMARDs. Specialist review by dermatologist, rheumatologist, and gastroenterologist.
CP.PHAR.264 Ustekinumab	Revised	Policy split from CP.PHAR.85.Psoriasis Treatments. Plaque psoriasis: removed criteria related to HBV, malignant disease and concurrent use with another biologic; modified requirement for the use of topical agent and phototherapy to not require 3 consecutive months of treatment; removed Otezla as a DMARD option for trial and failure; added requirement for failure of PDL Enbrel and Humira, unless contraindicated; added max dose requirement; updated contraindications per FDA labeling. Re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement; added max dose requirement. Psoriatic arthritis: modified criteria to require failure of PDL Enbrel and Humira, unless contraindicated; added max dose; updated contraindications per FDA labeling; required trial of MTX and added requirement for the following agents as an alternative if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. Re-auth: Combined into "All Indications"; added max dose and reasons to discontinue per PI;Shortened background section.
CP.PHAR.270 Paricalcitol	Revised	Removed requirement for oral calcitriol use prior to Zemplar due to lack of evidence to support that both agents are of clinical parity. Added limitation regarding concurrent administration with other vitamin D derivatives/analogs.
CP.PHAR.288 Eteplirsen	New	Policy created.
CP.PHAR.295 Sargramostim	New	Leukine is split from CP.PHAR.26.Colony Stimulating Factors 2015, and converted to a new template. Contraindications added per PI. Labeled use: post-consolidation for AML is not a labeled use so was removed. Off-label use: Treatment of MDS and FN prophylaxis removed per NCCN; posttransplant support added per NCCN; Neulasta limitation is added to FN treatment per NCCN.
CP.PHAR.296 Pegfilgrastim	New	Neulasta is split from CP.PHAR.26.Colony Stimulating Factors 2015, and converted to a new template. Max dose and contraindications added per PI. Labeled use: Acute radiation syndrome added per PI.Removed "Neulasta will not be given from 14 days before to 24 hours after chemotherapy." Off-label use: Posttransplant support added per NCCN.
CP.PHAR.297 Filgrastim Filgrastim-sndz Tbo-filgrastim	New	Granix, Neupogen, Zarxio are split from CP.PHAR.26.Colony Stimulating Factors 2015, and converted to a new template. Contraindications added per PIs. Under the labeled indication,

		"BMT," added "and bone marrow infusion." "PBPC collection" (section I.D), removed approval for use in subsequent transplant after collection; however, subsequent transplant will fall under off-label use, "supportive care in the post-hematopoietic cell transplant setting". Under sections I.A, B and C, 24-hour use restriction before and after chemotherapy is removed. Added oncology off-label uses per NCCN.
CP.PHAR.298 Afatinib	New	Policy created.
CP.PHAR.299 Gefitinib	New	Policy created.
CP.PHAR.300 Bezlotoxumab	New	Policy created.
CP.PHAR.301 Erwinia Asparaginase	New	Policy created.
CP.PHAR.302 Ixazomib	New	Policy created.
CP.PHAR.303 Brentuximab vedotin	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.304 Irinotecan Liposome Injection	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.305 Obinutuzumab	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.306 Ofatumumab	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.307 Bendamustine	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.308 Elotuzumab	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.309 Carfilzomib	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.310 Daratumumab	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.311 Belinostat	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.312 Blinatumomab	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.313 Pralatrexate	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.314 Romidepsin	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.315 Vincristine sulfate liposome inj	New	Policy split from CP.PHAR.182.Excellus Oncology.
CP.PHAR.316 Cabazitaxel	New	Policy split from CP.PHAR.182 Excellus Oncology.
CP.PHAR.317 Cetuximab	New	Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added. HNSCC subtypes by location outlined at Appendix B. CRC: EGFR testing is removed from the FDA labeled criteria. NRAS wild type (i.e., not mutated) is added to KRAS wild type. Some NCCN colon cancer off-label recommendations are collapsed and combined into a colorectal section with some rectal cancer indications.
CP.PHAR.327 Nusinersen	New	Policy created.