

CENTENE PHARMACY THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 CLINICAL POLICY (BIOPHARM) SUMMARY TABLE

Coverage Guideline/Policy & Procedure	Status	Revision Summary Description
CP.PHAR.14 Hydroxyprogesterone Caproate (Makena/compound)	Revised, 4/17 CPC	No criteria changes. Added compound to the title. Background section reformatted.
CP.PHAR.40 Octreotide Acetate (Sandostatin Injection, Sandostatin LAR Depot)	Revised, 3/17 CPC approved	The following criteria in section A “acromegaly” is removed: “If member has received pituitary irradiation Sandostatin LAR Depot will be withdrawn yearly for approximately 8 weeks to assess disease activity (if GH or IGF-1 levels increase and signs and symptoms recur Sandostatin LAR Depot therapy may be resumed).” Hypersensitivity removed as a contraindication. Acromegaly continuation criteria edited to allow 12 months of therapy before evidence of efficacy; renewal approval durations throughout policy are lengthened to 12 months. NCCN compendial uses added for carcinoids and VIPomas in section D.
CP.PHAR.43 Sapropterin Dihydrochloride (Kuvan)	Revised, 4/17 CPC	Removed contraindication of anaphylaxis to Kuvan due to verification challenges; Added a time frame for which Phe level will be considered valid.
CP.PHAR.59 Zoledronic Acid (Reclast, Zometa)	Revised, 3/17 CPC approved	Removed age restriction. Added maximum dose to continued therapy. Certain conditions representing potential contraindications to therapy and other safety criteria removed. Osteoporosis and Paget’s disease: Removed high risk of fracture (recent low-trauma hip fracture). Added “at total hip” to T score. Added requirement for T score/history of fracture to confirm diagnosis of male osteoporosis, and combined treatment of osteoporosis of postmenopausal women and males. Removed requirement for administration of calcium/vitamin D if appropriate. For Paget’s disease, removed requirement for trial/failure of an oral bisphosphonate. Hypercalcemia, multiple myeloma, and bone metastases: Removed requirement that multiple myeloma must be active, and deleted appendix C (definition of active MM). Removed CrCl < 30 (a warning) and hypercalcemia associated with hyperparathyroidism (a limitation of use) from contraindications. Added requirement for member to continue to be receiving oral calcium and vitamin D to continued therapy. Added reasons to discontinue to continued therapy
CP.PHAR.61 Cinacalcet (Sensipar)	Revised, 4/17 CPC approved	All indications: added prescriber specialty; added safety requirement related to contraindications per PI in lieu of the requirement that serum calcium \geq 8.4 mg/dL. Secondary HPT: added a time frame of within the last 3 months to iPTH criterion. Re-auth: removed requirements related to reasons to discontinue Sensipar therapy; added max dose. References updated.

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CP.PHAR.63 Everolimus (Afinitor, Afinitor Disperz)	Revised, 5/17 CPC approved	NCCN and FDA uses separated in criteria sets; dosing removed if NCCN uses added. NET: “Non-functional” designation removed for NET of GI and lung origin; the term “locally advanced” is incorporated into recurrent, unresectable or metastatic. RCC: The term “advanced” RCC is restated as recurrent, unresectable or metastatic. The term “unless contraindicated” is removed from “failed sunitinib or sorafenib treatment.” Safety information removed. Approval durations lengthened to 6 and 12 months.
CP.PHAR.80 Vandetanib (Caprelsa)	Revised, 3/17 CPC approved	Age restriction removed. The following cautions/contraindications are covered by the Caprelsa REMS program and so are not listed separately: Congenital long QT syndrome, Torsades de pointes, bradyarrhythmias, uncompensated heart failure, electrolyte monitoring, drug interactions, dosing. Safety criteria were removed unless they meet all the following: represent contraindications or black box warnings not covered by a REMS program, that can be objectively measured and diagnosed/ruled out with a single test.
CP.PHAR.91 Vemurafenib (Zelboraf)	Revised, 3/17 CPC approved	Age restriction removed. Wild type BRAF melanoma is removed as a limitation. Safety criteria were removed that did not either represent contraindications or black box warnings not covered by a REMS program; provide specific lab/imaging parameters that must be met prior to initiation of therapy; or can be diagnosed/ruled out with a single test.
CP.PHAR.93 Bevacizumab (Avastin)	Revised, 4/17 CPC approved	New FDA labeled indication added: Platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer. Doses removed. Under renal cell carcinoma, FDA approved use, added 2a/2b subtypes to interferon alpha. Safety criteria limited to black box warnings precluding initiation of therapy. Off-label ocular use is edited to follow supported uses in Micromedex and Clinical Pharmacology (i.e., AMD secondary to choroidal neovascularization, macular edema secondary to branch/central retinal vein occlusion or diabetes, choroidal retinal neovascularization secondary to pathologic myopia or angioid streaks, diabetic retinopathy, retinopathy of prematurity). Choroidal neovascularization associated with no known cause or with inflammation or ocular histoplasmosis syndrome is removed but may be requested under the Global Biopharm policy. Approval duration lengthened to 6 and 12 months. Added ICD-10 appropriate code ranges for eye conditions that now have a new 6th or 7th digit indicating the specific eye.
CP.PHAR.94 Alpha-1 Proteinase Inhibitors (Aralast NP, Glassia, Prolastin-C, Zemaira)	Revised, 3/17 CPC approved	Initial criteria: Age removed; conditions representing potential contraindications to therapy are removed.

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CP.PHAR.97 Eculizumab (Soliris)	Revised, 4/17 CPC approved	Removed requirement of Streptococcus pneumoniae and Haemophilus influenza type b (Hib) infections. Modified initial and approval duration to 6 months and 12 months respectively. Removed age requirements. Added max dose to continued approval criteria.
NH.PHAR.98 Ruxolitinib (Jakafi)	Revised, 4/17 CPC approved	Extended approval duration from 6 months to 12months.
NH.PHAR.100 Axitinib (Inlyta)	Revised, 3/17 CPC approved	Annual Review. No Changes
CP.PHAR.101 Mifepristone (Korlym)	Revised, 4/17 CPC approved	Removed age restriction. Removed lifestyle modification requirement. Duration of approval on re-auth changed from 6 months to 12 months.
CP.PHAR.109 Tesamorelin (Egrifta)	Revised, 3/17 CPC approved	Open epiphyses added in addition to age requirement as contraindication. Removed certain safety criteria, but retained contraindications per PI. Continued therapy duration extended to 12 months. Added formulations.
NH.PHAR.111 Cabozantinib (Cometriq, Cabometyx)	Revised, 4/17 CPC approved	Updated policy title to include Cabometyx.
CP.PHAR.114 Teduglutide (Gattex)	Revised, 4/17 CPC approved	Removed safety criteria that are not absolute contraindications or related to black box warnings. Removed age restriction. Removed contraindications in continued approval section.

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NH.PHAR.115 Pegloticase (Krystexxa)	Revised, 5/17 CPC approved	Annual Review. No Changes
CP.PHAR.119 Ramucirumab (Cyramza)	Revised, 4/17 CPC approved	Esophageal cancer added to section A. Lung cancer notations of specific required prior therapy are removed. Colorectal cancer indications updated around FDA and NCCN uses. Safety criteria removed as there are no contraindications or black box warnings precluding treatment. Changed initial approval duration to 6 months. Changed continued approval to 12 months.
CP.PHAR.121 Nivolumab (Opdivo)	Revised, 4/17 CPC approved	Two new labeled indications added: head and neck cancer and urothelial carcinoma (NCCN compendial uses added for both indications and for colorectal and small cell lung cancer). RCC NCCN recommended uses edited to include non-clear histology; for clear cell, “after tyrosine kinase inhibitor therapy” deleted. Safety criteria removed if not a contraindication or black box warning not covered by a REMS program. Reference to performance status removed.
CP.PHAR.126 Ibrutinib (Imbruvica)	Revised, 3/17 CPC approved	Added new FDA approved indication: MZL. MCL: added off-label use per NCCN compendium. CLL/SLL: removed “with or without 17p deletion” as that has no impact on coverage. Other diagnoses/indications: added hairy cell leukemia per NCCN compendium. Continued approval: Removed reasons to discontinue. Added requirement for documentation of positive response to therapy.
CP.PHAR.165 Ferumoxytol (Feraheme)	Revised, 3/17 CPC approved	Labeled and off-labeled use, and diagnostic/follow-up tests, are edited for consistency across ferumoxytol, ferric gluconate, iron sucrose, and ferric carboxymaltose policies, and are made broad enough to capture use in adults, children and pregnancy. The criteria also encompass iron maintenance and replenishment. Diagnostic hemoglobin for anemia in men changed from 13.5 to 13 based on WHO criteria. Age and dose are removed. Hypersensitivity removed as a contraindication.
CP.PHAR.166 Ferric Gluconate (Ferrlecit)	Revised, 3/17 CPC approved	Labeled and off-labeled use, and diagnostic/follow-up tests, are edited for consistency among ferumoxytol, ferric gluconate, iron sucrose, ferric carboxymaltose, and are made broad enough to capture use in adults, children and pregnancy. The criteria also encompass iron maintenance and replenishment. Diagnostic hemoglobin for anemia in men changed from 13.5 to 13 based on WHO criteria. Age and dose are removed. Hypersensitivity as a contraindication is removed.
CP.PHAR.167 Iron Sucrose (Venofer)	Revised, 3/17 CPC approved	Labeled and off-labeled use, and diagnostic/follow-up tests, are edited for consistency across among ferumoxytol, ferric gluconate, iron sucrose, ferric carboxymaltose, and are made broad enough to capture use in adults, children and pregnancy. The criteria

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		also encompass iron maintenance and replenishment. Diagnostic hemoglobin for anemia in men changed from 13.5 to 13. Age and dose are removed/ Hypersensitivity removed as a contraindication.
CP.PHAR.168 Repository Corticotropin Injection (H.P. Acthar Gel)	Revised, 5/17 CPC approved	Safety information removed. Infantile spasms approval duration is increased from 4 weeks to 3 months and continuing approval x 1 is added. MS approval duration is increased from 4 weeks to 3 months. Continued approval is per Medical Director review. Nephrotic syndrome criteria are added for recalcitrant cases. Other PI indications are added for recalcitrant cases with the qualification that requests be supplemented by peer-reviewed literature. Continued approval is per Medical Director review. References updated.
CP.PHAR.177 Ecallantide (Kalbitor)	Revised, 3/17 CPC approved	Added criteria to confirm diagnosis. Removed age requirement. Increased approval duration to 12 months, and incorporated recommended dosing from PI. Removed warning against hypersensitivity. Added criteria for continued approval.
CP.PHAR.178 Icatibant (Firazyr)	Revised, 3/17 CPC approved	Added criteria to confirm diagnosis. Removed age requirement. Increased approval duration to 12 months and added recommended dosing. Added criteria for continued approval.
CP.PHAR.179 Romiplostim (Nplate)	Revised, 3/17 CPC approved	Criteria: initial-removed age restriction. Added requirement for a hematologist to be involved in care. For Chronic ITP, changed platelet criteria to <30, and modified trial to require the use of the 2 first line agents: corticosteroid and IVIG. Certain conditions representing safety criteria removed as the PI does not specify a test/ objective method by which they should be evaluated. Retained verifiable lab finding useful to assess need for therapy and continuation of therapy.
CP.PHAR.180 Eltrombopag (Promacta)	Revised, 3/17 CPC approved	Removed age restriction. Added requirement for specialist to be involved in care. For Chronic ITP, changed platelet criteria to <30, and modified trial to require the use of the 2 first line agents: corticosteroid and IVIG. For HCV treatment induced ITP, changed platelet criteria to <75,000. Re-auth: added general efficacy statement and max dose requirement for each indication; removed certain monitoring criteria.
CP.PHAR.181 Hemin (Panhematin)	Revised, 3/17 CPC approved	Removed requirement that medication is prescribed by a physician experienced in porphyria. Removed warnings against hypersensitivity reactions. Removed exclusion to treatment because of the presence of porphyria cutanea tarda. Added examples of some clinical symptoms. Changed approval duration from 3 months to 14 days per PI.
CP.PHAR.184 Aflibercept (Eylea)	Revised, 3/17 CPC approved	Removed age requirement. Removed hypersensitivity safety criteria. For re-auth: modified “Currently receiving...” to “Previously received...”; modified documentation of positive response criterion to be open-ended; added criterion to verify that Eylea is not being used with other anti-VEGF therapies.

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CP.PHAR.185 Pegaptanib (Macugen)	Revised, 3/17 CPC approved	Removed age restriction. Removed hypersensitivity safety criteria. For re-auth: modified “Currently receiving...” to “Previously received...”; modified documentation of positive response criterion to be open-ended; added criterion to verify that Macugen is not being used with other anti-VEGF therapies.
CP.PHAR.186 Ranibizumab (Lucentis)	Revised, 3/17 CPC approved	Removed age restriction. Added new FDA-approved indication, mCNV; approval periods are set at 3 months. Removed hypersensitivity safety criteria. Modified “once a month” to “every 28 days.” For re-auth: modified “Currently receiving...” to “Previously received...”; modified documentation of positive response criterion to be open-ended; added criterion to verify that Lucentis is not being used with other anti-VEGF therapies.
CP.PHAR.187 Verteporfin (Visudyne)	Revised, 3/17 CPC approved	Removed age restriction. Removed restriction that lesion must be ≤ 5400 microns in greatest linear diameter for predominantly classic CNV. Added definition for occult CNV. Added option for contraindication/clinically significant adverse effects to anti-VEGF trial requirement. Removed max dose criterion, and instead incorporated dosing as a quantity limit (1 dose per 3 month approval period). Removed safety criteria. For continuation: Modified “Currently receiving...” to “Previously received...” to account for as needed dosing. Added requirement for documentation of positive response to therapy. Specified that FA should be at least 3 months after the last treatment.
CP.PHAR.188 Teriparatide (Forteo)	Revised, 3/17 CPC approved	Age requirement modified to apply to pediatric members with open epiphyses. Added “at total hip” to T score. Added that osteoporotic fracture should be confirmed by radiographic imaging. Removed requirement for administration of calcium/vitamin D. Removed conditions representing potential contraindications to therapy. Added dose to continued therapy. Added requirement for positive response to therapy.
CP.PHAR.189 Ibandronate Sodium (Boniva)	Revised, 3/17 CPC approved	Removed age restriction. Added “at total hip” to T score. Added that osteoporotic fracture should be confirmed by radiographic imaging. Certain conditions representing potential contraindications to therapy and other safety criteria removed. Removed requirement for administration of calcium/vitamin D if dietary intake is inadequate. Added dose to continued therapy. Added requirement for positive response to therapy.
CP.PHAR.190 Ambrisentan (Letairis)	Revised, 3/17 CPC approved	FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation criteria durations increased to 6 and 12 months respectively. Appendices covering PH group, functional class and therapy reorganized.

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CP.PHAR.191 Bosentan (Tracleer)	Revised, 3/17 CPC approved	FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they represent contraindications or black box warnings not covered by a REMS program, and provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH group, functional class and therapy reorganized.
CP.PHAR.192 Epoprostenol Sodium (Flolan, Veletri)	Revised, 3/17 CPC approved	FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH group, functional class and therapy reorganized.
CP.PHAR.193 Iloprost (Ventavis)	Revised, 3/17 CPC approved	FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH group, functional class and therapy reorganized.
CP.PHAR.194 Macitentan (Opsumit)	Revised, 3/17 CPC approved	Age restriction removed. FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH group, functional class and therapy reorganized.
CP.PHAR.195 Riociguat (Adempas)	Revised, 3/17 CPC approved	Age restriction removed. FC II added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement was added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH groups, functional class and therapies reorganized.
CP.PHAR.196 Selexipag (Uptravi)	Revised, 3/17 CPC approved	Age restriction removed. FC II added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is

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		added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH groups, functional class and therapies reorganized.
CP.PHAR.197 Sildenafil (Revatio)	Revised, 3/17 CPC approved	FC II added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH groups, functional class and therapies reorganized.
CP.PHAR.198 Tadalafil (Adcirca)	Revised, 3/17 CPC approved	FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH groups, functional class and therapies reorganized.
CP.PHAR.199 Trepstinil (Orenitram, Remodulin, Tyvasco)	Revised, 3/17 CPC approved	FC II is added to the prostanoid class of PH drugs. Safety criteria were removed unless they 1) represent contraindications or black box warnings not covered by a REMS program, and 2) provide specific lab/imaging parameters that must be met prior to initiation of therapy. An efficacy statement is added to the continuation criteria. Initial and continuation durations increased to 6 and 12 months respectively. Appendices covering PH group, functional class and therapy reorganized.
CP.PHAR.200 Mepolizumab (Nucala)	Revised, 4/17 CPC approved	Controller trial requirements are edited in the initial and renewal criteria and a smoking cessation line item is added. Efficacy statement is added to renewal criteria. Approval durations changed to 6 and 12 months.
CP.PHAR.201 Belatacept (Nulojix)	Revised, 3/17 CPC approved	Policy converted to new template. Added prescriber specialty requirement. Modified age requirement from > 18 to ≥ 18 years. Added requirement that Nulojix is prescribed for kidney transplant rejection prophylaxis. Added requirement related to tuberculosis screening per PI. Added general efficacy statement to continued approval section. Added max dose for maintenance phase.
CP.PHAR.202 Esterase Inhibitors (Berinert, Cinryze, Ruconest)	Revised, 3/17 CPC approved	Added criteria to confirm diagnosis. Removed age requirement. Increased approval duration to 12 months for Berinert/Ruconest and incorporated recommended dosing from PI. Added criteria for continued approval. Removed warnings against hypersensitivity reactions. For Cinryze, modified initial approval duration for long-term prophylaxis to 6 months and for renewal to 12 months. For continued therapy, added max dose criteria and reasons to discontinue.

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CP.PHAR.203 Cosyntropin (Cortrosyn)	Revised, 4/17 CPC approved	Removed requirement related to contraindications to cosyntropin (i.e., no hypersensitivity to any component, no allergic reaction or anaphylaxis to cosyntropin) from initial approval section. Added continuation criteria to clarify that continuation of therapy will not be granted and member must meet the initial approval criteria.
CP.PHAR.204 Trabectedin (Yondelis)	Revised, 4/17 CPC approved	Age and dose removed. Examples of anthracyclines added. Precautions removed given no black box warnings or contraindications other than hypersensitivity. Approval duration changed to 6 months and 12 months for initial and subsequent requests, respectively. NCCN recommended uses added.
CP.PHAR.205 Total Parenteral Nutrition and Intradialytic Parenteral Nutrition	Revised, 5/17 CPC approved	References reviewed and updated. Added 3 month time period for weight loss >10% of ideal body weight. Added that protein and albumin labs should be from last 4 weeks.
CP.PHAR.208 Sodium phenylbutyrate (Buphenyl)	Revised, 5/17 CPC approved	Specific UCDs are added to initial criteria; positive response to therapy is added to renewal criteria; duration of approval changed to 6 and 12 months for initial and continued approval, respectively.
CP.PHAR.209 Aztreonam (Cayston)	Revised, 5/17 CPC approved	FEV1 delineation of $\leq 90\%$ added to initial criteria. Allergy contraindication removed. B. cepacia restriction removed as it is not a contraindication. Efficacy statement edited to indicate a general positive response to therapy.
CP.PHAR.210 Ivacaftor (Kalydeco)	Revised, 5/17 CPC approved	Dosing criteria expanded by age. Efficacy statement edited to indicate general positive response to therapy.
CP.PHAR.211 Tobramycin (Bethkis Inhalation Solution, Kitabis Pak, TOBI Inhalation Solution, TOBI Podhaler)	Revised, 5/17 CPC approved	Bethkis added (limited distribution – see references for distribution network). Kitabis authorized generic added. FEV1 delineation of $\leq 90\%$ added to initial criteria. Allergy contraindication removed. Efficacy statement edited to indicate a general positive response to therapy.
CP.PHAR.212 Dornase Alfa (Pulmozyme)	Revised, 5/17 CPC approved	Efficacy statement edited to indicate general positive response to therapy.

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CP.PHAR.213 Lumacaftor-Ivacaftor (Orkambi)	Revised, 5/17 CPC approved	Age lowered to 6 years per PI – corresponding maximum dose added. Efficacy statement edited to indicate general positive response to therapy.
CP.PHAR.214 Desmopressin Acetate (DDAVP Injection)	Revised, 5/17 CPC approved	Trauma/surgery is separated from diabetes insipidus (DI). The nephrogenic DI restriction is removed. Age restriction is removed. The designation “mild to moderate” is removed from VWD. Safety information is removed with the exception of CrCl ₁ ; current hyponatremia as a contraindication is added. Wording for uses and approval periods for all blood factor products made consistent across all policies. Efficacy statement added to renewal criteria. Hemophilias are specified as “congenital” versus “acquired” across blood factor policies where indicated. Reviewed by specialist-hematology/internal medicine.
CP.PHAR.223 Reslizumab (Cinqair)	Revised, 4/17 CPC approved	An absolute blood eosinophil count ≥ 400 cells/mcL is added. Controller trial requirements are edited in the initial and renewal criteria and a smoking cessation line item is added. The contraindication/hypersensitivity black box warning of anaphylaxis is not included. Efficacy statement is added to renewal criteria. Approval durations changed to 6 and 12 months.
CP.PHAR.224 Enoxaparin (Lovenox)	Revised, 5/17 CPC approved	Section I.A. Criteria are edited to follow CHEST 2012 and 2016 in addition to labeled indications. Major additions include 1) prophylaxis: hip fracture, major orthopedic, general, cardiac, thoracic surgery, craniotomy; traumatic injury; critical illness; restricted mobility due to intracerebral hemorrhage, STEMI; a-fib, prosthetic heart valve; 2) treatment: PE; SVT; CVST; splanchnic thrombosis without cancer; nonbacterial thrombotic endocarditis. Warfarin bridging criteria are moved to renewal criteria. Safety information is removed. Section I.B. Removed required risk factors. Section II. Criteria are edited to follow CHEST 2016 guidelines. Major additions include 1) recurrent venous thrombosis on a non-low molecular weight heparin, 2) any other indication in section I.A., where bridging to warfarin is inappropriate or member has a contraindication to warfarin and extended (indefinite) anticoagulation therapy is required.

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<p>CP.PHAR.225 Dalteparin (Fragmin)</p>	<p>Revised, 5/17 CPC approved</p>	<p>Section I.A. Criteria are edited to follow CHEST 2012 and 2016 guidelines in addition to labeled indications. Major additions include 1) prophylaxis: hip fracture/knee replacement, major orthopedic, general, cardiac, thoracic surgery, craniotomy; traumatic injury; critical illness; restricted mobility due to intracerebral hemorrhage; a-fib; prosthetic heart valve; 2) treatment: SVT; CVST; splanchnic thrombosis without cancer; nonbacterial thrombotic endocarditis. Warfarin bridging criteria are moved to renewal criteria. Safety information is removed. Removed section I.B. Required risk factors associated with Cesarean. Added preferencing for enoxaparin. Section II. Criteria are edited to follow CHEST 2016 guidelines. Major additions include 1) recurrent venous thrombosis on a non-low molecular weight heparin, 2) any other indication in section I.A., where bridging to warfarin is inappropriate or member has a contraindication to warfarin and extended (indefinite) anticoagulation therapy is required.</p>
<p>CP.PHAR.226 Fondaparinux (Arixtra)</p>	<p>Revised, 5/17 CPC approved</p>	<p>Section I.A. Criteria are edited to follow CHEST 2012 and 2016 guidelines (which for the most part include NCCN and ACOG guidelines) in addition to labeled indications. Major additions include 1) prophylaxis: major orthopedic, general surgery; critical illness; restricted mobility due to acute illness; 2) treatment: SVT, splanchnic thrombosis without cancer. HIT is added to bypass enoxaparin preferencing. Warfarin bridging criteria are moved to renewal criteria. Safety information is removed; safety information is limited to black box warnings and contraindications that instruct a test be conducted to rule out a condition before starting therapy. Dosing is not added given the extent of off-label use in the policy. Section I.B. Pregnancy criteria are added for cases of HIT. Section II. Criteria are edited to follow CHEST 2016 guidelines. Major additions include 1) any other indication in section I.A., where bridging to warfarin is inappropriate or member has a contraindication to warfarin and extended (indefinite) anticoagulation therapy is required.</p>

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CP.PHAR.234 Ferric Carboxymaltose (Injectafer)	Revised, 3/17 CPC approved	Labeled and off-labeled use, and diagnostic/follow-up tests were edited for consistency among ferumoxytol, ferric gluconate, iron sucrose, ferric carboxymaltose, and were made broad enough to capture use in adults, children and pregnancy. The criteria also encompass iron maintenance versus replenishment. Diagnostic hemoglobin for anemia in men changed from 13.5 to 13. Age and dose removed. Hypersensitivity contraindication removed.
CP.PHAR.235 Atezolizumab (Tecentriq)	Revised, 5/17 CPC approved	New labeled indication added: first-line treatment of metastatic urothelial carcinoma in patients who are ineligible for cisplatin-containing chemotherapy.
CP.PHAR.318 Eribulin Mesylate (Halaven)	Revised, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added.
CP.PHAR.319 Ipilimumab (Yervoy)	Revised, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology. Off-label NCCN recommended uses added.
CP.PHAR.320 Necitumumab (Portrazza)	Revised, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology.
CP.PHAR.321 Panitumumab (Vectibix)	New, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added. CRC: NRAS wild type (i.e., not mutated) is added to KRAS wild type as NCCN notes recent evidence indicates that, like KRAS, NRAS mutations are predictive for a lack of benefit to panitumumab. KRAS and NRAS are members of the RAS human oncogene family. Some NCCN colon cancer off-label recommendations are collapsed and combined into a colorectal cancer section with some rectal cancer indications.
CP.PHAR.322 Pembrolizumab (Keytruda)	New, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology. Non-small cell lung cancer: NCCN off-label recommendations added; “recurrent or” added to “metastatic disease” and “or unknown” added to “negative mutation status” to consolidate criteria of those

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		FDA/NCCN uses that differed by the referenced terms. Head and neck cancers: NCCN off-label recommended uses added; subtypes by location outlined at Appendix B.
CP.PHAR.323 Plerixafor (Mozobil)	New, 3/17 CPC approved	Policy is split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended use in the allogeneic setting is added.
CP.PHAR.324 Temsirolimus (Torisel)	New, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology.
CP.PHAR.325 Ziv-Aflibercept (Zaltrap)	New, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added.
CP.PHAR.326 Olaratumab (Lartruvo)	New, 3/17 CPC approved	Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added.
CP.PHAR.328 Asfotase Alfa (Strensiq)	New, 3/17 CPC approved	New policy developed, specialist reviewed.
CP.PHAR.329 Siltuximab (Sylvant)	New, 3/17 CPC approved	Policy split from CP.PHAR.183 Excellus Other Specialty Pharmacy.
CP.PHAR.330 Protein C Concentrate, Human (Ceprotin)	New, 3/17 CPC approved	Policy split from CP.PHAR.183.Excellus Other Specialty Pharmacy. Added that prescriber with expertise in inherited thrombophilias may treat in addition to hematologist. Added a pathway to approval for presumptive diagnosis in acute setting. Extended approval criteria to 6 months for initial treatment.
CP.PHAR.331 Deflazacort (Emflaza)	New, 3/17 CPC approved	New policy.
CP.PHAR.332 Pasireotide (Signifor LAR)	New, 3/17 CPC approved	Policy split from CP.PHAR.183.Excellus Other Specialty Pharmacy. Initial therapy: “In consultation with” is added to “prescribed by an endocrinologist.” “Epiphyseal growth plates have closed” is added to “age ≥ 18 years.” Definition of full biochemical control is updated per the 2014 Endocrine Society guidelines and includes a tightening of random GH levels from < 2.5 ng/mL to < 1.0 ng/mL.2 Hepatic impairment restriction is added per PI. Dosing follows PI recommendations. Continued therapy: Demonstrated response does not include surgery outcomes, is not required until after 12 months of therapy, and is limited to any degree of improvement

CENTENE PHARMACY THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 CLINICAL POLICY (BIOPHARM) SUMMARY TABLE

		in biochemical control. Response criteria related to clinical features or comorbidities are not included as GH excess may be relatively asymptomatic.
CP.PHAR.333 Avelumab (Bavencio)	New, 4/17 CPC approved	New policy.
CP.PHAR.334 Ribociclib (Kisqali)	New, 4/17 CPC approved	New policy.
CP.PHAR.335 Ocrelizumab (Ocrevus)	Revised, 5/17 CPC approved	Changed requirement of failure of glatiramer acetate, Tecfidera, or Gilenya, to the following: Tecfidera or Gilenya and either an interferon-beta agent or glatiramer; or Tecfidera and Gilenya.
CP.PHAR.336 Dupilumab (Dupixent)	New, 5/17 CPC approved	New policy.
NH.PHAR.289 Buprenorphine Implant	Revised 7/17	Extended duration of approval to 12 months

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