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

Policy & Procedure	Type	Revision Summary or Description
CP.PHAR.41 Enfuvirtide	Revised	Policy converted to new template. Added maximum dose and contraindications per PI; added antiretroviral therapy regimen per DHHS; Modified criteria so that virologic failure defined by > 200 copies/ml of HIV RNA per DHHS guideline; added requirement for resistant test for patients with > 500 copies of HIV RNA on renewal criteria; added the need for continued treatment with other ARV to renewal criteria; added maximum dose requirement. Modified approval duration to 6 months and 12 months for initial and reauthorization criteria respectively.
CP.PHAR.84 Abiraterone	Revised	Policy converted to new template. Removed age and prescriber specialty requirements. Added max dose requirement. Updated reasons to discontinue. Approval duration changed to 6 months for initial and 12 months for renewal.
CP.PHAR.88 Belimumab	Revised	Converted policy to new template; modified approval criteria to 6 month and 12 months for initial and renewal criteria respectively. Added anaphylaxis with prior Benlysta administration as contraindication in initial and continuation criteria.
CP.PHAR.95 Thyrotropin alfa	Revised	Updated policy template. Combined diagnostic and therapeutic uses under one criteria set (“Thyroid Cancer”). Removed age restriction. Added max dosing criteria. Added continued criteria set. Added continued approval for diagnostic use. Approval duration for initial and continued is set at 6 months per NCCN monitoring recommendations.
NH.PHAR.105 Bosutinib	Reviewed	Annual Review, No Changes
NH.PHAR.106 Encalutamide	Reviewed	Annual Review, No Changes
CP.PHAR.145 Deferasirox	Revised	CP.PHAR.144 Jadenu incorporated into CP.PHAR.145 Exjade policy and converted to new template. Age removed and documentation requests added; “current documentation” is defined as “within the last 30 days” in the context of follow-up serum ferritin levels– 90 days is provided for follow-up LIC documentation request (section B). Section A: Initiation of therapy: the wording “and consistent ferritin levels >1,000” is changed to “or a serum ferritin level >1,000.” Section B: Jadenu preference over Exjade, in 2015 policy’s section A, is newly added to section B (Chronic Iron Overload Due to NTDT Syndromes). Approval durations for NTDT increased from 3 and 6 months to 6 and 12 months respectively. Serum ferritin and LIC options under continuation of therapy are consolidated for clarity. Definitions of “poor performance status” and “high-risk MDS” are removed.

CP.PHAR.146 Deferoxamine	Revised	Policy converted to new format. Added acute iron intoxication indication. Age removed and documentation requests added; "current documentation" defined as "within the last 30 days" for follow-up serum ferritin levels. Initiation of therapy: transfusion history and serum ferritin level per the PI dosing; the wording "and consistent ferritin levels >1,000" is changed to "or a serum ferritin level >1,000; examples of transfusion-dependent anemias added.
CP.PHAR.147 Deferiprone	Revised	Converted policy to new template. Age removed and documentation requests added; "current documentation" is defined as "within the last 30 days" for follow-up serum ferritin levels and recommended monthly ferritin tests. Initiation of therapy: transfusion history and serum ferritin level per the PI dosing information; the wording "and consistent ferritin levels >1,000" is changed to "or a serum ferritin level >1,000."
CP.PHAR.148 Rituximab Oncology Hematology	Revised	Converted to new format, including adding initial approval duration of 3 months and continued approval of 6 months. Removed codes and indications for pemphigus, lupus, Sjogren's, minimal change disease, granulomatosis with polyangiitis (Wegener's Granulomatosis), microscopic polyangiitis, RA and as these are not hematology or oncology indications. Distinguished between warm and cold autoimmune hemolytic anemia, and clarified that warm AIHA should be refractory to glucocorticoids (previously said refractory to conventional treatment). For thrombocytopenia purpura, added that Rituxan is second-line treatment. Criteria for NHL edited to match criteria for the same indications from CP.PHAR.260 Rituximab.
CP.PHAR.232 OnabotulinumtoxinA	Revised	Chronic migraine initial approval duration lengthened from 12 to 24 weeks (from one to two treatment sessions) to allow assessment of response as outlined in continuation criteria.
CP.PHAR.242 Adalimumab	Revised	PsO: Removed Otezla from list of therapies to trial per PDL.
CP.PHAR.245 Apremilast	New	Policy split from CP.PHAR.85.Psoriasis Treatment. Added prescriber specialty, max dose and contraindications per PI. Added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated; Removed question related to concurrent use with another biologic-not in contraindications section per PI. Modified prior treatment trial for PSA to require trial of MTX and added requirement for the following agents as an alternative if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine.Plaque Psoriasis: removed duration of trial for topical and phototherapy; added requirement for trial and failure of one oral systemic agent (e.g., MTX, cyclosporine or acitretin), unless contraindicated to such therapies; re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. Re-auth: combined into "All Indications", added max dose and reasons to discontinue per PI.
CP.PHAR.247 Certolizumab	New	Policy split from CP.PHAR.86.ArthritisTreatments, CP.PHAR.85 Psoriasis Treatment, CP.PHAR.87 IBD Treatment. CD, RA, PsA, AS: Removed criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines; added dosing requirement; added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated (just Humira for CD).

		PsA: required trial of MTX and added requirement for the following agents as an alternative if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. CD: removed aminosalicylate as an option for initial therapy. RA: changed age requirement to 18 years; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine and hydroxychloroquine as an alternative to MTX if MTX is contraindicated. Re-auth: combined into All Indications; added criteria for dosing and reasons to discontinue. Modified approval duration to 6 months for initial and 12 months for renewal. Shortened background section.
CP.PHAR.250 Etanercept	New	Policy split from CP.PHAR.85.Psoriasis Treatments and CP.PHAR.86.Arthritis Treatments. RA, PJIA, PsA, AS, PsO: Removed criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines; added dosing requirement. PJIA: removed question related to number of affected joints; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine as an alternative to MTX if MTX is contraindicated. RA: changed age requirement to 18; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine and hydroxychloroquine as an alternative to MTX if MTX is contraindicated. PsO: removed duration of trial for topical and phototherapy. PsA: required trial of MTX and added requirement for the following if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine & azathioprine.Re-auth: combined into All Indications; added dosing and reasons to discontinue; for PsO, changed efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. Removed Otezla from list of therapies to trial per PDL. Modified approval duration to 6 months for initial and 12 months for renewal.
CP.PHAR.253 Golimumab	Revised	PsA: Preferenced trial of MTX above other DMARDs per CPC feedback. UC: removed option of trial of aminosalicylates per 2015 AGA Clinical Care Pathway.
CP.PHAR.259 Natalizumab	Revised	Removed trial and failure of corticosteroid as an option for moderate to severe CD, per 2014 AGA Clinical decision tool- corticosteroids are appropriate for low-risk patients.
CP.PHAR.260 Rituximab	Revised	Added ICD-10 code table
CP.PHAR.261 Secukinumab	New	Policy split from CP.PHAR.85.Psoriasis Treatments. Plaque psoriasis: removed criteria related to malignant disease and concurrent use with another biologic agent; removed Otezla as an option for failure of DMARD; removed duration of trial for topical and phototherapy; added requirement for trial and failure of Enbrel and Humira, unless contraindicated; added max dose; updated contraindications per FDA labeling; re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. For PsA: required trial of MTX and added requirement for the following if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. Added criteria for coverage of ankylosing spondylitis and psoriatic arthritis. Re-auth: Combined into All Indications; added max dose and reasons to discontinue; Modified approval duration to 6 months for initial approval and 12 months for continued approval.
CP.PHAR.264 Ustekinumab	New	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.265 Vedolizumab	Revised	Removed trial and failure of corticosteroid as an option for moderate to severe CD, per 2014 AGA Clinical decision tool- corticosteroids are appropriate for low-risk patients. UC: removed option of trial of aminosalicylates per 2015 AGA Clinical Care Pathway.
CP.PHAR.287 Obeticholic Acid	New	Policy created.
CP.PHAR.289 Buprenorphine Implant	New	Policy created.