

CENTER FOR DRUG EVALUATION AND RESEARCH

**CLINICAL OUTCOME
ASSESSMENT (COA)
COMPENDIUM**

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Disclaimer

The Clinical Outcome Assessment (COA) Compendium is a communication tool and it is intended to serve as a starting point when considering a COA for use in clinical trials. The inclusion of a COA in the COA Compendium does not equate to an endorsement by FDA and does not represent agency guidance.

Drug sponsors are strongly encouraged to seek advice from the relevant Office of New Drug (OND) review division early in drug development to discuss the selection and implementation of COAs specific to their program. This is irrespective of whether the disease, condition, indication, claim, or COA is included in the COA Compendium.

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Limitations of the COA Compendium include, but are not limited to:

- It is not a comprehensive list of COAs and is not intended to replace either existing disease-specific guidance or key interactions with FDA concerning drug development (e.g., during pre-IND meetings)
- Inclusion of a COA in the COA Compendium does not necessarily indicate that the measure is or should be the primary or sole determinant of effectiveness in a clinical trial nor is it indicative of endpoint positioning (e.g., primary or secondary)
- The COA Compendium presents information that was available at the time it was compiled and updated; it may not include newer COAs that could be recommended for a drug development program, or more recent scientific and regulatory thinking
- It does not include biomarkers with the exception of biomarkers used in composite endpoints
- It does not include measures of survival with the exception of use in composite endpoints
- It does not include the endpoint definition of labeled COAs
- Some of the COAs listed in the COA Compendium may be protected by proprietary rights and, in some cases, a royalty and fee may be charged by the copyright owners for their authorized use

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COA COMPENDIUM DESCRIPTION

This COA Compendium is part of FDA’s efforts to foster patient-focused drug development. The COA Compendium is intended to facilitate communication and to provide clarity and transparency to drug developers and researchers by collating and summarizing COA information for many different diseases and conditions into a single resource. We suggest using the COA Compendium as a starting point when considering a COA for use in clinical trials.

The COA Compendium is a table that:

- Describes how certain COAs have been used in clinical trials to measure the patient’s experience (such as disease-related symptoms) and to support labeling claims.
- Identifies COAs that have been qualified for potential use in multiple drug development programs under CDER’s [Drug Development Tool \(DDT\) Qualification Program](#).

This is the second update to the Compendium since the launch of the pilot in January 2016. The update is an extension of the original document and includes COAs from three major sources:

- Labeling of new molecular entity (NME) drugs and biological license application (BLA) drugs approved from July 2017 to June 2019 collected through Drugs@FDA
- Efficacy supplements pertaining to a new indication and/or new population approved from July 2017 to June 2018 collected through Drugs@FDA
- Qualified measures based on CDER’s COA DDT Qualification Program collected through the Qualification Website for Qualified COAs

The [COA Compendium](#) is organized by CDER’s OND offices and review divisions. The table alphabetically lists conditions or diseases based on each review division’s therapeutic assignment. The gray shaded rows describe information about a [COA DDT qualification project](#).

COLUMNS	ELEMENTS	DESCRIPTION OF CONTENT
Column 1	Disease/Condition	Lists disease or condition
Column 2	COA Context of Use	Describes circumstance under which the COA has been used (i.e., labeled) or has been qualified (for qualified tools under CDER’s DDT Qualification program)
Column 3	Concept	Describes the concept that the COA measures
Column 4	COA Tool & Type	Describes the: <ul style="list-style-type: none"> • COA as listed in labeling or the qualification statement • COA Type (i.e., a patient-reported outcome, observer-reported outcome, clinician-reported outcome, or performance outcome tool) Tools listed in Column 3 were found in labeling for all drugs listed in Column 5, with the exception of those denoted with a superscript
Column 5	Drug Name & Approval Date	List the brand and generic name of approved drugs, date of approval for NME labeling and the most recent approval date for efficacy supplements.

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A **clinical outcome assessment (COA)** is defined as an assessment of a clinical outcome that can be made through report by a clinician, a patient, a non-clinician observer or through a performance-based assessment. The [FDA-NIH BEST Glossary](#) defines them as:

Clinician-reported outcome (ClinRO): A measurement based on a report that comes from a trained health-care professional after observation of a patient's health condition.

Patient-Reported outcome (PRO): A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else.

Observer-reported outcome (ObsRO): A measurement based on a report of observable signs, events or behaviors related to a patient's health condition by someone other than the patient or a health professional.

Performance outcome (PerfO): A measurement based on standardized task(s) actively undertaken by a patient according to a set of instructions.

A biomarker is a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how an individual feels, functions, or survives.

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OFFICE OF CARDIOLOGY, HEMATOLOGY, ENDOCRINOLOGY, AND NEPHROLOGY (OCHEN)

DIVISION OF CARDIOLOGY AND NEPHROLOGY (DCN)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/Qualification Link
Acute coronary syndrome (ACS)	Adults with ACS	<ul style="list-style-type: none"> • Incidence of cardiovascular death • Non-fatal myocardial infarction • Non-fatal stroke 	Composite: ClinRO	1. Brilinta (ticagrelor) <i>July 20, 2011</i> 2. Effient (prasugrel) <i>July 10, 2009</i>
Acute myocardial infarction	Adults receiving percutaneous coronary intervention	<ul style="list-style-type: none"> • All-cause mortality • Myocardial infarction • Ischemia-driven revascularization • Stent thrombosis 	Composite: ClinRO	Kengreal (cangrelor) <i>June 22, 2015</i>
Atrial fibrillation (AF) /atrial flutter (AFL)	Adults in sinus rhythm with a history of paroxysmal or persistent AF/AFL	Hospitalization due to cardiovascular cause or death from any cause	Composite: ClinRO	Multaq (dronedaronone HCL) <i>July 1, 2009</i>
		First symptomatic AF/AFL recurrence	Composite: ClinRO	
Autosomal dominant polycystic kidney disease (ADPKD)	Adults at risk of rapidly progressing ADPKD	Time to multiple clinical progression: <ul style="list-style-type: none"> • Worsening kidney function • Medically significant kidney pain • Worsening hypertension • Worsening albuminuria 	Composite: <ul style="list-style-type: none"> • Biomarker • ClinRO • ClinRO • Biomarker 	Jynarque (tolvaptan) <i>April 23, 2018</i>

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DIVISION OF CARDIOLOGY AND NEPHROLOGY (DCN) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Cardiomyopathy	Adults with cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis	<ul style="list-style-type: none"> All-cause mortality Frequency of cardiovascular-related hospitalizations 	Composite: ClinRO	Vyndaqel (tafamidis meglumine) May 3, 2019
		Frequency of cardiovascular-related hospitalizations	Composite: ClinRO	
		Functional capacity	6-Minute Walk Test (6MWT): PerfO	
		Health status	Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score: PRO	
Chronic coronary artery disease	Adults with a history of atherosclerosis involving the coronary, cerebral, or peripheral vascular systems	<ul style="list-style-type: none"> Incidence of cardiovascular death, myocardial infarction and stroke Avoidance of hospitalization for unstable angina Avoidance of coronary revascularization 	Composite: ClinRO	Zontivity (vorapaxar) May 8, 2014
Chronic heart failure (CHF)	Limited Context of Use See qualification statement for additional information	CHF symptoms and their impact on physical limitations	PRO	Qualified COA Kansas City Cardiomyopathy Questionnaire (KCCQ) Visit " Clinical Outcome Assessment (COA) Qualification Program Qualified Clinical Outcome Assessments " Website for additional information

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Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Chronic stable angina	Adults with chronic angina	Exercise duration	Modified Bruce Treadmill Exercise test: PerfO	Ranexa (ranolazine) <i>January 27, 2006</i>
		Angina attack frequency	Diary: PRO	
		Nitroglycerin use	Diary: PRO	
Chronic thromboembolic pulmonary hypertension (CTEPH)	Adults with CTEPH	Exercise capacity	6-Minute Walking Distance (6MWD): PerfO	Adempas (riociguat) <i>October 8, 2013</i>
		World Health Organization functional class / lack of deterioration	World Health Organization functional assessment: ClinRO	
Heart failure	Adults with chronic heart failure	Composite as first event <ul style="list-style-type: none"> Cardiovascular death Hospitalization due to heart failure 	Composite: ClinRO	1. Corlanor (ivabradine) <i>April 15, 2015</i> 2. Entresto (sacubitril and valsartan) <i>July 7, 2015</i>
Neurogenic orthostatic hypotension	Adults with symptomatic neurogenic orthostatic hypotension	Symptom severity (e.g., dizziness, lightheadedness, feeling faint, and “feeling like you might blackout”)	Orthostatic Hypotension Questionnaire Item (OHQ) #1: PRO	Nothera (droxidopa) <i>February 18, 2014</i>
Non-valvular atrial fibrillation (NVAf)	Adults with NVAf	<ul style="list-style-type: none"> Stroke Systemic embolic event 	Composite: ClinRO	1. Savaysa (edoxaban) <i>January 8, 2015</i> 2. Eliquis (apixaban) <i>December 28, 2012</i> 3. Xarelto (rivaroxaban) <i>November 4, 2011</i> 4. Pradaxa (dabigatran) <i>October 19, 2010</i>

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Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Pulmonary arterial hypertension (PAH)	Adults with PAH	Exercise capacity	6-Minute Walking Distance (6MWD): Perfo ^{2,3,4,5}	1. Uptravi (selexipag) <i>December 21, 2015</i>
		Incidence of death or clinical deterioration	ClinRO ^{2,3,4,5}	2. Opsumit (macitentan) <i>October 18, 2013</i>
		<ul style="list-style-type: none"> Incidence of PAH Worsening of PAH 	Composite ¹ <ul style="list-style-type: none"> Hospitalization for PAH: ClinRO PAH worsening resulting in need for lung transplantation or balloon atrial septostomy: ClinRO 	3. Adempas (riociguat) <i>October 8, 2013</i> 4. Letairis (ambrisentan) <i>June 15, 2007</i> 5. Ventavis (iloprost) <i>December 29, 2004</i>
Patients with a history of atherosclerosis	Adult patients with a history of atherosclerosis involving the coronary, cerebral, or peripheral vascular systems	<ul style="list-style-type: none"> Incidence of cardiovascular death, myocardial infarction, and stroke Avoidance of hospitalization for unstable angina Avoidance of coronary revascularization 	Composite: ClinRO	Zontivity (vorapaxar) <i>May 8, 2014</i>
Varicose veins	Adult patients with spider or reticular varicose veins	Improvement of varicose veins	Digital photographs of the treatment area: ClinRO	Asclera (polidocanol) <i>March 30, 2010</i>
		Patient satisfaction with treatment	5-point verbal rating scale: PRO	

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DIVISION OF DIABETES, LIPID DISORDERS AND OBESITY (DDLO)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Cardiovascular risk associated with established cardiovascular disease	Adults with established cardiovascular disease	<ul style="list-style-type: none"> • Cardiovascular death • Myocardial infarction • Stroke • Hospitalization for unstable angina • Coronary revascularization 	Composite: ClinRO	Repatha (evolocumab) <i>August 27, 2015</i> <i>December 1, 2017</i>
Cardiovascular risk associated with type 2 diabetes mellitus (T2DM) and established cardiovascular disease	Adults with type 2 diabetes mellitus (T2DM) and established cardiovascular disease	<ul style="list-style-type: none"> • Cardiovascular death • Non-fatal myocardial infarction • Non-fatal stroke 	Composite: ClinRO	Victoza (liraglutide) <i>January 25, 2010</i> <i>August 25, 2017</i>
Type 2 diabetes mellitus (T2DM) and atherosclerotic cardiovascular disease	Adults with T2DM and atherosclerotic cardiovascular disease	Severe hypoglycemia outcomes	ClinRO	Tresiba (insulin degludec) <i>September 25, 2015</i> <i>March 26, 2018</i>

DIVISION OF GENERAL ENDOCRINOLOGY (DGE)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Human immunodeficiency virus (HIV)-related lipodystrophy	Adult patients with HIV-related lipodystrophy	Body image	Belly appearance distress score: PRO	Egrifta (tesamorelin) <i>November 10, 2010</i>

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DIVISION OF NON-MALIGNANT HEMATOLOGY (DNH)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Acquired thrombotic thrombocytopenic purpura (aTTP)	Adults with aTTP, in combination with plasma exchange and immunosuppressive therapy	<ul style="list-style-type: none"> • Recurrence of TTP (exacerbation) • Treatment-emergent major thromboembolic event • TTP-related death 	Composite: ClinRO	Cablivi (caplacizumab-yhdp) <i>February 6, 2019</i>
Hemophilia A	Adult and adolescent males (aged 12 to 75 years) with hemophilia A and FVIII inhibitors who previously received either episodic (on-demand) or prophylactic treatment with bypassing agents	Frequency of bleeding requiring treatment with coagulation factors	ClinRO	Hemlibra (emicizumab-kxwh) <i>November 16, 2017</i>
	Adults with hemophilia A and FVIII inhibitors who previously received either episodic (on-demand) or prophylactic treatment with bypassing agents	Health related quality of life-physical health	Haemophilia-specific Quality of Life (Haem-A-QoL) Physical Health Score: PRO	
Iron deficiency anemia	Adults with iron deficiency anemia who have intolerance to oral iron or have had unsatisfactory response to oral iron	Disease-related fatigue	Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-fatigue): PRO	Feraheme (ferumoxytol) <i>June 30, 2009</i> <i>February 2, 2018</i>

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Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Myelofibrosis (MF)	Patients with intermediate or high risk MF, post polycythemia-vera MF and post essential thrombocythemia MF who are symptomatic	MF symptom severity (e.g., tiredness, night sweats, itchiness, abdominal discomfort, pain under the ribs, feeling of fullness, bone or muscle pain)	Myelofibrosis Symptoms Assessment Form (MF-SAF) diary*: PRO	Jakafi (ruxolitinib) <i>November 16, 2011</i> <i>October 10, 2017</i>
		Fatigue-related symptoms and associated impacts on daily activities	PROMIS-Fatigue 7-item short form (PROMIS-Fatigue 7b): PRO	
Paroxysmal nocturnal hemoglobinuria (PNH)	Adult patients with PNH and hemolysis requiring transfusion	Disease-related fatigue	Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-fatigue): PRO	1. Soliris (eculizumab) <i>March 16, 2007</i> 2. Ultomiris (ravulizumab-cwvz) <i>December 21, 2018</i>
		Transfusion avoidance	ClinRO ²	
Primary hemophagocytic lymphohistocytosis (HLH)	Adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy	Overall response rate	ClinRO/Biomarker	Gamifant (emapalumab-lzsg) <i>November 20, 2018</i>
Thrombocytopenia	Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	Need for rescue medication or procedure	ClinRO	1. Doptelet (avatrombopag) <i>May 21, 2018</i> 2. Mulpleta (lusutrombopag) <i>July 31, 2018</i>

*MFSAF v4.0 is the currently recommended version instead of v2.0 which was used in the Jakafi approval

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Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Venous thromboembolism (VTE)	Prophylaxis of VTE in adult patients	DVT/PE related symptomatic events: <ul style="list-style-type: none"> Asymptomatic proximal Deep Vein Thrombosis (DVT) (detected by ultrasound) Symptomatic proximal or distal DVT Non-fatal Pulmonary Embolism (PE), or VTE-related death 	Composite ¹ <ul style="list-style-type: none"> Biomarker ClinRO ClinRO ClinRO 	1. Bevyxxa (betrixaban) <i>June 23, 2017</i> 2. Savaysa (edoxaban) <i>January 8, 2015</i> 3. Xarelto (rivaroxaban) <i>July 1, 2011</i>
		DVT/PE related symptomatic events: <ul style="list-style-type: none"> Recurrent DVT New non-fatal symptomatic PE Fatal PE 	Composite: ClinRO ²	
		DVT/PE related symptomatic events: <ul style="list-style-type: none"> Recurrent DVT Non-fatal PE Fatal PE 	Composite: ClinRO ³	

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OFFICE OF IMMUNOLOGY AND INFLAMMATION (OII)

DIVISION OF DERMATOLOGY AND DENTISTRY (DDD)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Acne vulgaris	Patients 9 years of age and older with inflammatory lesions of non-nodular moderate- to-severe acne vulgaris	Global assessment of the overall severity of the disease (e.g., clear or almost clear)	Investigator's Global Assessment: ClinRO	Seysara (sarecycline) <i>October 1, 2018</i>
		Inflammatory lesion count	ClinRO	
Actinic keratosis (topical therapy)	Adult patients with actinic keratosis	Clearance of actinic keratosis lesions	ClinRO	Picato (ingenol mebutate) <i>January 23, 2012</i>
	Adult patients with actinic keratoses of the upper extremities			Levulan kerastick (amino-levulinic acid hydrochloride) <i>December 3, 1999</i> <i>March 6, 2018</i>
Atopic dermatitis	Adults with moderate-to-severe atopic dermatitis	Global assessment of the overall severity of the disease (e.g., erythema and papulation/infiltration)	Investigator's Global Assessment: ClinRO	Dupixent (dupilumab) <i>March 28, 2017</i> <i>April 10, 2018</i>
		Extent and severity of the disease (e.g., thickness, scratching and lichenification)	Eczema Area and Severity Index (EASI-75): ClinRO	
		Itching intensity	Pruritus Numeric Rating Scale (NRS): PRO	
Atopic dermatitis	Patients 2 years of age and older with mild-to-moderate atopic dermatitis	Global assessment of the overall severity of the disease (e.g., clear or almost clear)	Investigator's Static Global Assessment: ClinRO	Eucrisa (crisaborole) <i>December 14, 2016</i>

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DIVISION OF DERMATOLOGY AND DENTISTRY (DDD) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
External genital and perianal warts (topical therapy)	Adult patients with external genital and perianal warts	Clearance of external genital and perianal warts	ClinRO	Veregen (kunecatechins) <i>October 31, 2006</i>
Forehead lines	Adults with forehead lines	Forehead line severity at maximum eyebrow elevation	Facial Wrinkle Scale with Photonumeric Guide: ClinRO	Botox Cosmetic (OnabotulinumtoxinA) <i>December 9, 1991</i> <i>October 2, 2017</i>
		Forehead line severity at maximum eyebrow elevation	Facial Wrinkle Scale with Photonumeric Guide: PRO	
		Facial line satisfaction	Facial Line Satisfaction Questionnaire: PRO	
Glabellar lines	Adults with moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	Glabellar line severity at maximum frown	Glabellar Line Scale (GLS): PRO	Jeuveau (prabotulinumtoxinA-xvfs) <i>February 1, 2019</i>
		Glabellar line severity at maximum frown	Glabellar Line Scale (GLS): ClinRO	
Head lice infestation (topical therapy)	Pediatric and adult patients with head lice infestation	Absence of live lice	ClinRO	1. Natroba (spinosad) <i>January 18, 2011</i> 2. Ulesfia 5% Lotion (benzyl alcohol) <i>April 9, 2009</i>

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DIVISION OF DERMATOLOGY AND DENTISTRY (DDD) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Interdigital tinea pedis, tinea cruris, tinea corporis (topical therapy)	Pediatric and/or adult patients with interdigital tinea pedis, tinea cruris, and/or tinea corporis	<ul style="list-style-type: none"> Clearance of signs and symptoms (e.g., erythema, scaling, and pruritus) Mycological cure (fungal culture and potassium hydroxide (KOH) tests) 	Composite ¹ <ul style="list-style-type: none"> ClinRO & PRO Laboratory measure: Biomarker(s) Note: pruritus symptoms are assessed based on patient-reported outcome 	1. Luzu cream 1% (luliconazole) <i>November 14, 2013</i> <i>February 20, 2018</i> 2. Ertaczo (sertaconazole nitrate cream 2%) <i>December 10, 2003</i>
		Clearance of signs and symptoms (e.g., erythema, scaling, and pruritus)	PRO² & ClinRO²	
Onychomycosis (topical therapy)	Adults patients with onychomycosis	Composite <ul style="list-style-type: none"> Clinical evidence of the disease (absence of signs/symptoms) Mycological cure (fungal culture and potassium hydroxide (KOH) tests) 	Composite <ul style="list-style-type: none"> ClinRO Laboratory measures: Biomarker(s) 	1. Kerydin (Tavaborole) <i>July 7, 2014</i> 2. Jublia (efinaconazole) <i>June 6, 2014</i>
Pemphigus vulgaris	Adults with pemphigus vulgaris	Complete remission: <ul style="list-style-type: none"> Complete epithelialization and absence of new and/or established lesions Discontinuation of prednisone therapy 	ClinRO	Rituxan (rituximab) <i>November 26, 1997</i> <i>June 7, 2018</i>

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DIVISION OF DERMATOLOGY AND DENTISTRY (DDD) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Plaque psoriasis	Adults with moderate-to-severe plaque psoriasis	Extent and severity of affected body surface area (e.g., induration, erythema, and scaling)	Psoriasis Area and Severity Index (PASI): ClinRO ^{1,2,3,4,5,6,7}	1. Siliq (brodalumab) <i>February 15, 2017</i>
		Global assessment of the overall severity of the disease (e.g., plaque thickness/induration, erythema, and scaling)	Physician's Global Assessment: ClinRO ^{1,2,3,4,5,6,7}	2. Taltz (ixekizumab) <i>March 22, 2016</i>
		Symptoms of plaque psoriasis	Psoriasis Symptom Inventory (PSI): PRO ¹	3. Cosentyx (secukinumab) <i>January 21, 2015</i> <i>January 23, 2018</i>
		Itching severity	Itch numeric Rating Scale: PRO ²	4. Tremfya (guselkumab) <i>July 13, 2017</i>
		Patient-reported symptoms	Psoriasis Symptom Diary: PRO ³	5. Ilumya (tildrakizumab-asmn) <i>March 20, 2018</i>
		Symptoms of psoriasis (itch, pain, stinging, burning and skin tightness)	Psoriasis Symptoms and Signs Diary (PSSD): PRO ⁴	6. Skyrizi (risankizumab-rzaa) <i>April 23, 2019</i>
		Global assessment of the overall severity of the disease of the scalp	Scalp specific Investigator's Global Assessment Scale: ClinRO ⁴	7. Cimzia (certolizumab pegol) <i>April 22, 2008</i> <i>May 24, 2018</i>
		Signs and symptoms related to pain, redness, itching and burning	Psoriasis Symptom Scale (PSS): PRO ⁶	
		Global assessment of the overall severity of the disease of the scalp	Investigator Global Assessment scalp only score: ClinRO ³	

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DIVISION OF DERMATOLOGY AND DENTISTRY (DDD) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Plaque psoriasis	Patients 12 years or older with plaque psoriasis	Extent and severity of affected body surface area (e.g., induration, erythema, and scaling)	Psoriasis Area and Severity Index (PASI): ClinRO	Stelara (ustekinumab) <i>October 13, 2017</i>
		Global assessment of the overall severity of the disease (e.g., induration, erythema and scaling)	Physician's Global Assessment: ClinRO	
Submental fat	Adults with moderate-to-severe convexity or fullness associated with submental fatvere convexity or fullness	Improvement in submental convexity or fullness	Composite <ul style="list-style-type: none"> • Clinician-Reported Submental Fat Rating ScaleFat Rating Scale (CR-SMFRS): ClinRO • Patient-Reported Submental Fat Rating Scale (PR-SMFRS): PRO 	Kybella (deoxycholic acid) <i>April 29, 2015</i>
		Visual and emotional impact of submental fat	Six-question survey: PRO	

DIVISION OF GASTROENTEROLOGY (DG)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Bowel prep	Adults scheduled for elective colonoscopy	Successful (excellent or good) bowel prep (visualization of mucosa and minimal need for additional suctioning or washing)	ClinRO	Prepopik (citric acid; magnesium oxide; sodium picosulfate) <i>July 16, 2012</i>

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DIVISION OF GASTROENTEROLOGY (DG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Carcinoid syndrome diarrhea	Adults with carcinoid syndrome diarrhea	Frequency of bowel movement	Diary: PRO	Xermelo (telotristat ethyl) <i>February 28, 2017</i>
		Abdominal pain		
		Flushing		
Carcinoid syndrome diarrhea	Adults with carcinoid syndrome diarrhea	Use of rescue therapy	Diary: PRO	Somatuline Depot (lanreotide) <i>August 30, 2007</i> <i>September 15, 2017</i>
		Frequency of diarrhea and flushing symptoms		
Chronic idiopathic constipation (CIC)	Adults with CIC	Frequency of complete spontaneous bowel movements (CSBM)	Diary: PRO ^{1,2,4}	1. Trulance (plecanatide) <i>January 19, 2017</i> 2. Linzess (linaclotide) <i>August 30, 2012</i> 3. Amitiza (lubiprostone) <i>January 31, 2006</i> 4. Motegrity (prucalopride) <i>December 14, 2018</i>
		Frequency of spontaneous bowel movements (SBM)	Diary: PRO ^{1,2,3}	
		Straining—amount of time pushing or physical effort to pass stool	Diary: PRO ¹	
		Stool consistency	Bristol Stool Form Scale (BSFS): PRO ^{1,2}	
		Signs and symptoms related to constipation (e.g., abdominal pain, stool consistency, severity of straining)	Numeric rating scale assessing signs and symptoms: PRO ^{2,3}	
Crohn's disease (CD)	Adults with CD	<ul style="list-style-type: none"> Signs and symptoms of the disease Disease activity 	Composite: <ul style="list-style-type: none"> PRO & ClinRO Biomarkers 	1. Cimzia (certolizumab pegol) <i>April 22, 2008</i> 2. Entyvio (vedolizumab) <i>May 20, 2014</i>

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DIVISION OF GASTROENTEROLOGY (DG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Diary for irritable bowel syndrome symptoms — constipation (DIBSS-C)	Adults (18 years or older) with IBS-C	<ul style="list-style-type: none"> Bowel movement (BM)-related symptoms (i.e., BM frequency, stool consistency, incomplete BMs, and straining) Abdominal symptoms (i.e., abdominal pain, abdominal discomfort, and bloating) 	PRO	Qualified COA Diary for Irritable Bowel Syndrome Symptoms-Constipation (DIBSS-C) Visit “ Clinical Outcome Assessment (COA) Qualification Program Qualified Clinical Outcome Assessments ” Website for additional information
Irritable bowel syndrome with constipation (IBS-C)	Adults with IBS-C	Frequency of complete spontaneous bowel movements (CSBM)	Diary: PRO	1. Linzess (linaclotide) <i>August 30, 2012</i> 2. Trulance (plecanatide) <i>January 19, 2017</i> <i>January 24, 2018</i>
		Abdominal pain intensity	11-point abdominal pain numeric rating scale: PRO	
Irritable bowel syndrome with diarrhea (IBS-D)	Adults with IBS-D	Abdominal pain intensity and stool consistency	Composite <ul style="list-style-type: none"> Diary: PRO Bristol Stool Scale (BSS): PRO 	Viberzi (eluxadoline) <i>May 27, 2015</i>
			11-point abdominal pain numeric rating scale: PRO	

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DIVISION OF GASTROENTEROLOGY (DG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Nausea and vomiting associated with chemotherapy	Adults with delayed nausea and vomiting associated with emetogenic chemotherapy ²	Absence of vomiting, retching or nausea and no use of rescue medication ²	Diary: PRO ^{1,2}	1. Aloxi (palonosetron hydrochloride) <i>July 25, 2003</i> 2. Varubi (rolapitant) <i>September 1, 2015</i>
	Adults at risk for nausea and vomiting associated with emetogenic chemotherapy ¹	Absence of emetic episodes and no use of rescue medication ¹		
Nausea and vomiting associated with chemotherapy	Adults with acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy	Complete Response: <ul style="list-style-type: none"> • Emetic episodes • Use of rescue medication 	Diary: PRO	Akynzeo (fosnetupitant and palonosetron) <i>April 19, 2018</i>
Non-infectious diarrhea	Adults with noninfectious diarrhea, HIV related	Stool consistency	Bristol Stool Form Scale: PRO	Mytesi (crofelemer) <i>December 31, 2012</i>
		Frequency of the watery bowel movement	Patient diary: PRO	
Opioid induced constipation	Adults with opioid induced constipation	Frequency of spontaneous bowel movements without laxative use	Diary: PRO ^{1,2}	1. Amitiza (lubiprostone) <i>January 31, 2006</i> <i>April 19, 2013</i> 2. Symproic (naldemedine) <i>March 23, 2017</i>
		Frequency of complete spontaneous bowel movement	Diary: PRO ²	
Opioid induced ileus, postoperative	Adults with opioid induced ileus, postoperative	Resolution of opioid induced ileus, both the upper and lower gastrointestinal tract (i.e., toleration of solid food and first bowel movement)	Diary: PRO	Entereg (alvimopan) <i>May 20, 2008</i>

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DIVISION OF GASTROENTEROLOGY (DG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Pancreas divisum undergoing endoscopic retrograde cholangiopancreatography (ERCP)	Adults with pancreas divisum undergoing ERCP	Cannulation of the minor duct of the pancreas	ClinRO	Chirhostim (secretin synthetic human) <i>April 9, 2004</i>
Ulcerative colitis	Adults with moderate to severely active UC	Disease activity and severity	Endoscopy: ClinRO	1. Entyvio (vedolizumab) <i>May 20, 2014</i>
		Signs and symptoms of UC (blood and stool frequency)	Diary: PRO	2. Xeljanz (tofacitinib) <i>November 6, 2012</i> <i>May 30, 2018</i>

DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Allergic rhinitis	Pediatric and adult patients with allergic rhinitis	Nasal symptoms severity (e.g., runny nose, nasal itching, sneezing, and nasal congestion)	4-point categorical nasal symptom severity scale: PRO	Omnaris (ciclesonine) <i>October 20, 2006</i>

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DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Asthma	Limited context of use See qualification statement for additional information	Severity of asthma symptoms	PRO	Qualified COA Asthma Daytime Symptom Diary (ADSD) and Asthma Nighttime Symptom Diary (ANSD) Visit " Clinical Outcome Assessment (COA) Qualification Program Qualified Clinical Outcome Assessments " Website for additional information
Asthma	Patients 6 years of age and older for the maintenance treatment of asthma	Signs and symptoms of asthma and adequacy of asthma control	Asthma Control Questionnaire (ACQ-7) • Asthma symptoms: PRO	Spiriva Respimat (tiotropium bromide) <i>February 15, 2017</i>
		Health Related Quality of life	Asthma Quality of Life Questionnaire (AQLQ): PRO	
		Signs and symptoms of asthma and measure of asthma exacerbation	Composite: Asthma exacerbation • Peak Expiratory Flow (PEF): Biomarker • Asthma symptoms: PRO	
Asthma	Patients with asthma 6 to less than 12 years of age	Functional problems related to asthma (physical, emotional and social)	Pediatric Asthma Quality of Life Questionnaire (PAQLQ): PRO	Symbicort (budesonide/formoterol) <i>January 27, 2017</i>

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DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Asthma	Adults with severe asthma with an eosinophilic phenotype for add on maintenance treatment	Functional problems related to asthma	Asthma Quality of life questionnaire (AQLQ): PRO	Cinqair (reslizumab) <i>March 23, 2016</i>
		Adequacy of and change in asthma control	Asthma Control Questionnaire (ACQ-7): PRO	
		Asthma exacerbation	Composite: ClinRO <ul style="list-style-type: none"> • Use or increase in the use of a systemic corticosteroid • Asthma-related emergency treatment or asthma-related hospitalization 	
Asthma	Patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype as an add-on maintenance treatment	Asthma exacerbation	Composite: ClinRO ^{1,2} <ul style="list-style-type: none"> • Use of oral/systemic steroids • Increase in the use of oral/systemic corticosteroids² • Hospitalization • Emergency department visits 	1. Nucala (mepolizumab) <i>November 4, 2015</i> 2. Fasenra (benralizumab) <i>November 14, 2017</i>
		Asthma control	Asthma Control Questionnaire-5 (ACQ-5): PRO ¹	
			Asthma Control Questionnaire-6 (ACQ-6): PRO ²	

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Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Asthma (continued)		Functional problems related to asthma	Standardized Asthma Quality of Life Questionnaire for 12 years and Older (AQLQ(S)+12): PRO ²	
		Symptoms frequency and severity, physical activity limitations, and impact on daily life	St. Georges Respiratory Questionnaire (SGRQ): PRO ¹	
		Reduction in oral corticosteroid use	ClinRO ²	
Asthma	Pediatric and adult patients with asthma	Frequency and severity of asthma exacerbation	Diary: PRO	Xolair (omalizumab) <i>June 20, 2003</i>
		Lung function	FEV1: Biomarker	
		Improvement in asthma symptoms severity	Asthma symptoms score: PRO	
Asthma	Patients with asthma 12 years of age and older	Asthma exacerbation	Composite: ClinRO <ul style="list-style-type: none"> • Use of systemic corticosteroids • Hospitalization • Emergency department visits 	1. Symbicort (budesonide/formoterol) <i>January 27, 2017</i> <i>December 20, 2017</i> 2. Dulera (mometasone and formoterol) <i>June 22, 2010</i> <i>December 20, 2017</i>
Asthma	Patients aged 5 years to 11 years old	Use of rescue medication	Diary: PRO and/or ObsRO as appropriate	Arnuity Ellipta (fluticasone furoate) <i>August 20, 2014</i> <i>May 17, 2018</i>

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DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Chronic obstructive pulmonary disease (COPD)	Limited context of use See qualification statement for additional information	Respiratory symptoms of stable COPD	PRO	Qualified COA Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease (E-RS: COPD) Visit " Clinical Outcome Assessment [COA] Qualification Program Qualified Clinical Outcome Assessments " Website for additional information
Chronic obstructive pulmonary disease (COPD)	Adult patients with COPD	Symptoms frequency and severity, physical activity limitations, and impact on daily life	St. George's Respiratory Questionnaire: PRO ^{2,4,6} St. George's Respiratory Questionnaire for COPD patients (SGRQ-C): PRO ⁵	<ol style="list-style-type: none"> 1. Breo Ellipta (fluticasone furoate and vilanterol trifenate) <i>May 10, 2013</i> 2. Arcapta Neohaler (indacaterol maleate) <i>July 1, 2011</i> 3. Daliresp (roflumilast) <i>February 28, 2011</i> <i>August 31, 2017</i> 4. Yupelri (revefenacin) <i>November 9, 2018</i> 5. Trelegy Ellipta (fluticasone, meclidinium, and vilanterol) <i>September 18, 2017</i> <i>April 24, 2018</i> 6. Symbicort (budesonide/formoterol) <i>January 27, 2017</i> <i>September 11, 2017</i>
		<ul style="list-style-type: none"> • Symptoms of exacerbation • Therapeutic intervention • Hospitalization • Death^{3,5} 	Composite of pulmonary exacerbations: ClinRO ^{1,3,5,6}	
		Reduction in rescue medication use	Diary: PRO ⁵	

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DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Cystic fibrosis	Patients age 12 years and older with cystic fibrosis (CF)	Respiratory symptoms (cough, sputum production, difficulty breathing)	Cystic Fibrosis Questionnaire – Revised (CFQ-R) Respiratory Domain: PRO	1. Orkambi (lumacaftor/ivacaftor) <i>July 2, 2015</i>
		Sino-pulmonary signs and symptoms of exacerbation	Pulmonary exacerbation: ClinRO	2. Symdeko (tezacaftor/ivacaftor) <i>February 12, 2018</i>
Cystic fibrosis	Pediatric and adult patients with cystic fibrosis	Respiratory symptoms severity	Cystic Fibrosis Questionnaire – Revised respiratory domain (CFQ-R): PRO	Kalydeco (ivacaftor) <i>January 31, 2012</i> <i>May 17, 2017</i> <i>July 31, 2017</i>
		Sino-pulmonary signs and symptoms of exacerbation	Pulmonary exacerbation: ClinRO	

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DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Eosinophilic granulomatosis with polyangiitis (EGPA)	Adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)	Remission	Birmingham Vasculitis Activity Score (BVAS): ClinRO Oral corticosteroid use: ClinRO	Nucala (mepolizumab) <i>November 4, 2015</i> <i>December 12, 2017</i>
		Time to first relapse: <ul style="list-style-type: none"> • Vasculitis activity • Asthma control • Sino-nasal symptoms • Corticosteroid use • Immunosuppressive therapy • Hospitalization 	Composite (Worsening): <ul style="list-style-type: none"> • Birmingham Vasculitis Activity Score (BVAS): ClinRO • Asthma Control Questionnaire-6 ACQ-6: PRO • Diary: PRO • ClinRO • ClinRO • ClinRO 	
		Reduction of oral corticosteroid use	ClinRO	
		Asthma control	Asthma Control Questionnaire-6 (ACQ-6): PRO	

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DIVISION OF PULMONOLOGY, ALLERGY AND CRITICAL CARE (DPACC) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Hereditary angioedema (HAE)	Pediatric and adult patients with HAE	Signs and symptoms severity (e.g., skin swelling, skin pain, abdominal pain)	100mm visual analog scale or evaluating each sign/symptom severity: PRO ¹	1. Firazyr (icatibant acetate) <i>August 25, 2011</i> 2. Kalbitor (ecallantide) <i>December 1, 2009</i>
			4-point categorical scale (Mean Symptom Complex Severity score): PRO ²	
		Improvement of each anatomic site of attack	Categorical scale evaluating treatment improvement (Treatment Outcome Score): PRO ²	
Hereditary angioedema (HAE)	Prophylaxis for patients age 12 years and older to prevent HAE	HAE attacks	ClinRO	Takhzyro (lanadelumab-flyo) <i>August 23, 2018</i>
Idiopathic pulmonary fibrosis (IPF)	Adult patients with idiopathic pulmonary fibrosis	IPF exacerbation (defined as worsening or development of dyspnea and imaging abnormalities)	Composite • ClinRO and Biomarker	Ofev (nintedanib) <i>October 15, 2014</i>
Respiratory distress syndrome (RDS)	Premature infants at high risk for RDS	Prevention of RDS in premature infants at high risk for RDS	Incidence of RDS and RDS related mortality: ClinRO	*Surfaxin (lucinactant) <i>March 6, 2012</i>

*Surfaxin is no longer marketed but the clinical outcome assessment is still considered acceptable.

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DIVISION OF RHEUMATOLOGY AND TRANSPLANT MEDICINE (DRTM)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Ankylosing spondylitis	Adult patients with ankylosing spondylitis	Signs and symptoms of ankylosing spondylitis (e.g., pain, inflammation)	Composite: Assessment in Ankylosing Spondylitis (ASAS): PRO ^{1,2}	1. Simponi (golimumab) <i>April 24, 2009</i> 2. Simponi Aria (golimumab) <i>July 18, 2013</i> <i>October 20, 2017</i>
			<ul style="list-style-type: none"> • VAS pain scale • Bath Ankylosing Spondylitis Functional Index • Bath Ankylosing Spondylitis Disease Activity Index • Patient global assessment 	
			Bath Ankylosing Spondylitis Disease Activity Index: PRO ²	
		Bath Ankylosing Spondylitis Metrology Index: ClinRO ²		
		General health status	Short Form (SF-36): PRO ²	
Health-related quality of life	Ankylosing Spondylitis Quality of Life questionnaire (ASQoL): PRO ²			
Cryopyrin-associated periodic syndromes (CAPS)	Pediatric and adult patients with CAPS	Signs and symptoms severity (e.g., rash, fatigue, joint pain, feeling of fever/chills, eye redness/pain)	Severity rating of each symptom on a 0-10-point scale with half point increments on the Daily Health Assessment Form: PRO ²	1. Ilaris (canakinumab) <i>June 17, 2009</i> 2. Arcalyst (rilonacept) <i>February 27, 2008</i>
		Physician global assessment of disease activity and skin disease assessment	Physician's global rating using a categorical rating scale: ClinRO ¹	

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DIVISION OF RHEUMATOLOGY AND TRANSPLANT MEDICINE (DRTM) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Kidney transplantation (prophylaxis of organ rejection)	Patients with kidney transplant	Composite <ul style="list-style-type: none"> • Incidence of biopsy-proven acute rejection • Death • Graft loss • Patient loss to follow up 	Composite <ul style="list-style-type: none"> • ClinRO • ClinRO • Biomarker • Patient loss to follow up 	Nulojix (beletcept) <i>June 15, 2011</i>
Psoriatic arthritis (PsA)	Adults with active PsA	<ul style="list-style-type: none"> • Improvement in number of tender and swollen joints • Pain intensity • Patient's global assessment of disease activity • Physician's global assessment of disease activity • Disability • Physical functioning • Laboratory measure (Biomarker(s)) (e.g., sedimentation rate) 	American College of Rheumatology (ACR) core set of outcome measures: [ClinRO, PRO and Biomarker] ^{1,2,3,4,5,6}	1. Orencia (abatacept) <i>June 30, 2017</i> 2. Otezla (apremilast) <i>March 21, 2014</i> 3. Simponi (golimumab) <i>April 24, 2009</i> 4. Simponi Aria (golimumab) <i>July 18, 2013</i> <i>October 20, 2017</i> 5. Xeljanz (tofacitinib) <i>November 6, 2012</i> <i>December 14, 2017</i> 6. Taltz (ixekizumab) <i>March 22, 2016</i> <i>December 1, 2017</i>
		Physical function	Health Assessment Questionnaire Disability Index (HAQ-DI): PRO ^{1,2,3,4,5,6}	
		General health status	Short Form (SF-36): PRO ^{4,5,6}	
		Improvement in enthesitis	Leeds Enthesitis Index: ClinRO ⁴	

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DIVISION OF RHEUMATOLOGY AND TRANSPLANT MEDICINE (DRTM) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Rheumatoid arthritis (RA)	Adult patients with RA	<ul style="list-style-type: none"> Improvement in number of tender and swollen joints Pain intensity Patient's global assessment of disease activity Physician's global assessment of disease activity Disability Physical functioning Laboratory measure (Biomarker(s)) (e.g., sedimentation rate) 	Composite <ul style="list-style-type: none"> American College of Rheumatology (ACR) core set of outcome measures: [ClinRO, PRO, and Biomarker(s)]^{1,2,3,4,5,6} 	1. Kevzara (sarilumab) <i>May 22, 2017</i> 2. Simponi Aria (golimumab) <i>July 18, 2013</i> 3. Xeljanz (tofacitinib) <i>November 6, 2012</i> 4. Actemra (tocilizumab) <i>January 8, 2010</i> 5. Orencia (abatacept) <i>December 23, 2005</i> 6. Olumiant (baricitinib) <i>May 31, 2018</i>
		<ul style="list-style-type: none"> Number of tender joints Number of swollen joints Patient global assessment of disease activity Laboratory measure (Biomarker(s)) (e.g., sedimentation rate) 	Composite: Disease Activity Score (DAS)-28: [ClinRO, PRO and Biomarker(s)] ⁶	
		Physical function	Health Assessment Questionnaire Disability Index (HAQ-DI): PRO ^{1,2,3,4,5,6}	
		General health status	Short Form (SF-36): PRO ^{1,5,6}	

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DIVISION OF RHEUMATOLOGY AND TRANSPLANT MEDICINE (DRTM) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Systemic lupus erythematosus	Patients with systemic lupus erythematosus	Signs and symptoms and disease activity severity	Composite <ul style="list-style-type: none"> • Systemic Lupus Erythematosus Disease Activity Index: ClinRO • British Isles Lupus Activity Group: ClinRO • Clinician's Global Assessment: ClinRO 	Benlysta (belimumab) <i>March 9, 2011</i> <i>July 20, 2017</i>
		Global impression		
		Time to first severe flare	Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) Flare Index (SFI): ClinRO	
		Prednisone reduction		

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OFFICE OF INFECTIOUS DISEASE (OID)

DIVISION OF ANTI-INFECTIVES (DAI)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Acute bacterial exacerbation of chronic bronchitis in patients with COPD (ABECB-COPD)	Limited Context of Use See qualification statement for additional information	Symptoms of ABECB-COPD (breathlessness, cough and sputum, chest symptoms, difficulty bringing up sputum, tired or weak, sleep disturbance, scared or worried)	PRO	Qualified COA Exacerbations of Chronic Pulmonary Disease Tool (EXACT) Visit " Clinical Outcome Assessment (COA) Qualification Program Qualified Clinical Outcome Assessments " Website for additional information
Acute bacterial skin and skin structure infections (ABSSSI)	Adults with acute bacterial skin and skin structure infections (ABSSSI)	Reduction in lesion size	ClinRO	Nuzyra (omadacycline) <i>October 2, 2018</i>
		Resolution of infection		
Acute otitis externa	Patients 6 months of age and older with Acute Otitis Externa due to <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i>	Resolution of signs and symptoms of acute otitis externa (tenderness, erythema, edema, and otorrhea)	ClinRO	Otiprio (ciprofloxacin) <i>December 10, 2015</i> <i>March 2, 2018</i>
Bacterial vaginosis	Adult women with bacterial vaginosis	Clinical Response: <ul style="list-style-type: none"> normal vaginal discharge negative whiff test clue cells <20% 	Composite <ul style="list-style-type: none"> ClinRO and Biomarker 	Solosec (secnidazole) <i>September 15, 2017</i>
<i>Clostridioides difficile</i> infection	Adult patients with <i>Clostridioides difficile</i>	Sustained clinical response post initial treatment	ClinRO	Zinplava (bezlotoxumab) <i>October 21, 2016</i>

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DIVISION OF ANTI-INFECTIVES (DAI) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
<i>Clostridioides difficile</i> -associated diarrhea	Adult patients with <i>Clostridioides difficile</i>	Improvement in diarrhea or other symptoms (e.g., unformed stool count)	ClinRO	Difucid (fidaxomicin) <i>May 27, 2011</i>
		Sustained clinical response post initial treatment	ClinRO	
Community-acquired bacterial pneumonia (CABP)	Adults with community-acquired bacterial pneumonia (CABP)	Survival with improvement in at least two of four symptoms without deterioration in any of the symptoms (cough, sputum production, chest pain, dyspnea)	ClinRO	Nuzyra (omadacycline) <i>October 2, 2018</i>
Complicated intra-abdominal Infections (cIAI)	Adults with complicated intra-abdominal infections proven or strongly suspected to be caused by susceptible bacteria	Complete resolution or significant improvement of signs or symptoms of the index infection	ClinRO	Xerava (eravacycline) <i>August 27, 2018</i>
Complicated urinary tract Infections (cUTI)	Adults with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible bacteria	Clinical Cure: • Resolution or improvement of the symptoms of cUTI present at trial entry (and no new symptoms)	Composite: • ClinRO and Biomarker	1. Vabomere (meropenem and vaborbactam) <i>August 29, 2017</i> 2. Zemdri (plazomicin) <i>June 25, 2018</i>
		Microbiological Eradication		
Cystic fibrosis (CF)	Patients with CF age 7 years and above	Changes in respiratory symptoms (cough, wheezing, sputum production)	CF Questionnaire—Revised (CFQ-R) respiratory domain: PRO	Cayston (aztreonam) <i>February 22, 2010</i>

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DIVISION OF ANTI-INFECTIVES (DAI) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Fascioliasis	Patients 6 years of age and older with fascioliasis	Absence of Fasciola eggs in the stool	Biomarker	Egaten (triclabendazole) <i>February 13, 2019</i>
		Resolution of signs and symptoms	ClinRO	
Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)	Adults with HABP/VABP	All-cause mortality	ClinRO	Avycaz (ceftazidime and avibactam) <i>February 25, 2015</i> <i>February 1, 2018</i>
		Resolution or significant improvement in signs and symptoms associated with pneumonia		
Impetigo	Adult and pediatric patients with impetigo	Absence or improvement of treated lesions	ClinRO	1. Altabax (retapamulin) <i>April 12, 2007</i> 2. Xepi (ozenoxacin) <i>December 11, 2017</i>
Leishmaniasis (cutaneous, mucosal and visceral)	Adolescents and adult patients with cutaneous leishmaniasis	Resolution of edema, erythema, infiltration and erosion and/or epithelialization of lesions	ClinRO	Impavido (miltefosine) <i>March 19, 2014</i>
		No enlargement of lesions or no appearance of new lesions		
		Clearance of the parasites	Laboratory Measure: Biomarker	

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DIVISION OF ANTI-INFECTIVES (DAI) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Malaria (<i>Plasmodium vivax</i>)	Patients aged 16 years and older receiving appropriate antimalarial therapy for acute <i>P. vivax</i> infection	Prevention of relapse: <ul style="list-style-type: none"> Initial parasite clearance No additional anti-malarial medication use Confirmed parasite-free at 6-month final assessment 	Composite ClinRO and Biomarker	Krintafel (tafenoquine) <i>July 20, 2018</i>
Travelers' diarrhea	Adults with travelers' diarrhea caused by noninvasive strains of <i>E. coli</i>	Clinical response based on time to last unformed stool Resolution of symptoms	PRO	1. Xifaxan (rifaximin) <i>May 25, 2004</i> 2. Aemcolo (rifamycin) <i>November 16, 2018</i>

DIVISION OF ANTIVIRALS (DAV)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Acute uncomplicated influenza	Treatment of acute uncomplicated influenza	Symptoms of Influenza: (cough, sore throat, nasal congestion, headache, feverishness, myalgia and fatigue)	Diary: PRO	Xofluza (baloxavir marboxil) <i>October 24, 2018</i>
Acute uncomplicated influenza	Treatment of acute uncomplicated influenza in adult patients	Symptoms of Influenza: (cough, sore throat, nasal congestion, headache, feverishness, myalgia and fatigue)	Diary: PRO	Rapivab (peramivir) <i>December 19, 2014</i> <i>September 20, 2017</i>
	Treatment of acute uncomplicated influenza in pediatric patients	Signs and symptoms of Influenza	Diary: PRO or ObsRO , as appropriate	

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OFFICE OF NEUROSCIENCE (ON)

DIVISION OF NEUROLOGY I AND II (DN I AND II)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Alzheimer's disease (AD)	Adult patients with moderate to severe AD	Day-to-day function	Modified Alzheimer's Disease Cooperative Study—Activities of Daily Living: ClinRO	Namenda (memantine hydrochloride) <i>October 16, 2003</i>
		Cognitive function	Severe Impairment Battery (SIB): PerfO	
		Global impression	Clinical Global Impression of change: ClinRO	
Amyotrophic lateral sclerosis (ALS)	Adults with ALS	Functional disability	ALS Functional Rating Scale-revised (ALSFRS-R): ClinRO	Radicava (edaravone injection) <i>May 5, 2017</i>
Blepharospasm	Adults with blepharospasm	Signs and symptoms of blepharospasm	Jankovic Rating Scale (JRS)-severity domain: ClinRO	Xeomin (incobotulinumtoxinA) <i>July 30, 2010</i>
Cervical dystonia	Adults with cervical dystonia	<ul style="list-style-type: none"> Severity of dystonia Disability Pain 	Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) (composite of ClinRO and PRO)	1. Xeomin (incobotulinumtoxinA) <i>July 30, 2010</i> 2. Dysport (abobotulinumtoxinA) <i>April 29, 2009</i>

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Duchenne muscular dystrophy (DMD)	Children (5 years and up) and adults with DMD	Muscle strength	Medical Research Council (MRC) 11-point scale: ClinRO ¹	1. Emflaza (deflazacort) <i>February 9, 2017</i> 2. Exondys 51 (eteplirsen) <i>September 19, 2016</i>
		Physical function speed	Timed functional tests: Perfo ¹	
		Walking distance	6 Minute Walk Test (6MWT): Perfo ²	
Generalized myasthenia gravis (gMG)	Adults with generalized myasthenia gravis	Impact on daily function	Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL): PRO	Soliris (eculizumab) <i>March 16, 2007</i> <i>October 23, 2017</i>
		Muscle weakness	Quantitative Myasthenia Gravis (QMG) Score: Multicomponent ClinRO/Perfo/Biomarker	
Huntington's chorea	Adults with chorea associated with HD	Chorea	Total chorea score item of the Unified Huntington's Disease Rating Scale (UHDRS): ClinRO	Austedo (deutetrabenazine) <i>April 3, 2017</i>
		Global impression	Patient-rated Global Impression: PRO	
		Global impression	Physician-rated Clinical Global Impression: ClinRO	
Huntington's disease (HD)	Adults with chorea associated with HD	Chorea	Total chorea score item of the Unified Huntington's Disease Rating Scale (UHDRS): ClinRO	Xenazine (tetrabenazine) <i>August 15, 2008</i>
		Global impression	Clinical Global Impression: ClinRO	

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Lambert-Eaton myasthenic syndrome (LEMS)	Adults with Lambert-Eaton myasthenic syndrome (LEMS)	Muscle weakness	Quantitative Myasthenia Gravis (QMG) Score: Multicomponent ClinRO/PerfO/Biomarker	Firdapse (amifampridine phosphate) <i>November 28, 2018</i>
		Global impression of the effects of the study treatment on physical well-being	Subject Global Impression: PRO	
		Global impression of improvement	Clinical Global Impression of Improvement: ClinRO	
Migraine headache	Adults and adolescents (12 years and up) with migraine headaches	Migraine frequency	Diary: PRO	1. Trokendi XR (topiramate) <i>August 16, 2013</i> <i>April 5, 2017</i>
				2. Qudexy XR (topiramate) <i>March 11, 2014</i> <i>March 29, 2017</i>
	Adults with migraine headaches	Migraine frequency	Diary: PRO	Aimovig (erenumab-aooe) <i>May 17, 2018</i>
Migraine headache (episodic)	Adults with a history of episodic migraines	Migraine frequency	Diary: PRO	1. Ajovy (fremanezumab-vfrm) <i>September 14, 2018</i> 2. Emgality (galcanezumab-gnlm) <i>September 27, 2018</i>

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Migraine headache (chronic)	Adults with a history of chronic migraines	<ul style="list-style-type: none"> • Migraine frequency • Headache frequency 	Diary: PRO	1. Ajovy (fremanezumab-vfrm) <i>September 14, 2018</i>
		Impact of migraine on daily activities	Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQv2.1) Role Function-Restrictive domain: PRO ²	2. Emgality (galcanezumab-gnlm) <i>September 27, 2018</i>

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Multiple sclerosis (MS)	Adults with primary progressive forms of MS	Physical disability	Expanded Disability Status Scale (EDSS): ClinRO	Ocrevus (ocrelizumab) <i>March 28, 2017</i>
		Walking speed	Timed 25-foot walk: PerfO	
	Patients 10 to less than 18 years of age with relapsing-remitting multiple sclerosis	Relapse frequency	ClinRO	Gilenya (fingolimod hydrochloride) <i>September 21, 2010</i> <i>May 11, 2018</i>
	Adults with relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease	Physical Disability	Expanded Disability Status Scale (EDSS) score: ClinRO	Mayzent (siponimod fumaric acid) <i>March 26, 2019</i>
		Relapse frequency	ClinRO	
		Walking Speed	25-foot walk test: PerfO	
	Adults with relapsing forms of MS	Relapse frequency	ClinRO	1. Ocrevus (ocrelizumab) <i>March 28, 2017</i> 2. Zinbryta (daclizumab) <i>May 27, 2016</i> 3. Tecfidera (dimethyl fumarate) <i>March 27, 2013</i> 4. Aubagio (teriflunomide) <i>September 12, 2012</i> 5. Gilenya (fingolimod) <i>September 21, 2010</i>
		Physical disability	Expanded Disability Status Scale (EDSS): ClinRO	

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Multiple sclerosis (MS)	Adults with MS	Walking speed	Timed 25-foot walk: PerfO	Ampyra (dalfampridine) <i>January 22, 2010</i>
		Ambulatory disability	12-item Multiple Sclerosis Walking Scale: PRO	
Parkinson's disease (PD)	Adults with PD experiencing "off" episodes	Signs and symptoms of dyskinesia	Diary: PRO	Xadago (safinamide) <i>March 21, 2017</i>
		Motor function	Uniform Parkinson's Disease Rating Scale (UPDRS) Part III (motor examination): ClinRO	
Parkinson's disease (PD) (Early Stage)	Adults with PD	Motor findings	Uniform Parkinson's Disease Rating Scale (UPDRS) Part III (motor examination): ClinRO	1. Neupro (rotigotine) <i>May 9, 2007</i> 2. Azilect (rasagiline mesylate) <i>May 16, 2006</i>
		Activities of daily living	Unified Parkinson's Disease Rating Scale (UPDRS)—Part II: ClinRO	
Parkinson's disease (PD) (Advanced stage)	Adults with PD	"Off" time	Patient diary: PRO Unified Parkinson's Disease	1. Azilect (rasagiline mesylate) <i>May 16, 2006</i> 2. Apokyn (apomorphine HCl) <i>April 20, 2004</i>
		Motor findings	Unified Parkinson's Disease Rating Scale (UPDRS)—Part III: ClinRO ^{1,2}	
		Activities of daily living	Unified Parkinson's Disease Rating Scale (UPDRS)—Part II: ClinRO ¹	

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Polyneuropathy of hereditary transthyretin-mediated amyloidosis	Adults with polyneuropathy of hereditary transthyretin-mediated amyloidosis	Neuropathy impairment	modified Neuropathy Impairment Score +7 (mNIS+7): Multicomponent ClinRO/Biomarker	1. Onpattro (patisiran sodium) <i>August 10, 2018</i> 2. Tegsedi (inotersen sodium) <i>October 5, 2018</i>
		Patient experience of neuropathy in the following domains: Physical functioning/large fiber neuropathy, activities of daily living, symptoms, small fiber neuropathy, and autonomic neuropathy	Norfolk Quality of Life-Diabetic Neuropathy total score (QoL-DN): PRO	
Restless legs syndrome (RLS)	Adults with moderate to severe primary RLS	Sensory and motor symptom severity and impacts on sleep, daytime tiredness or sleepiness, activities of daily living, and mood associated with RLS	International Restless Legs Syndrome (RLS) Rating Scale: PRO	Horizant (gabapentin enacarbil) <i>April 6, 2011</i>
		Global impression-RLS symptoms	Clinical Global Impression: ClinRO	
Seizure disorder	Adults and pediatrics 6 years and up with partial onset or primary generalized tonic-clonic seizures	Seizure frequency	Diary: PRO and/or ObsRO as appropriate	Trokendi XR (topiramate) <i>August 16, 2013</i> <i>April 5, 2017</i>
	Adults and pediatrics 15 years and up with partial onset or primary generalized tonic-clonic seizures			Briviact (brivaracetam) <i>February 18, 2016</i>

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Seizure disorder: Dravet syndrome	Patients 2–18 years of age with Dravet syndrome	Convulsive seizure frequency (all countable atonic, tonic, clonic, and tonic-clonic seizures)	Diary: PRO and/or ObsRO as appropriate	Epidiolex (cannabidiol) <i>June 25, 2018</i>
Seizure disorder: Dravet syndrome	Patients 3 years of age and older with seizures associated with Dravet syndrome taking clobazam	Generalized clonic or tonic-clonic seizure frequency Seizure frequency	Diary: PRO and/or ObsRO as appropriate	Diacomit (stiripentol) <i>August 20, 2018</i>
Seizure disorder: Infantile spasm	Pediatric (1 month–2 years) patients with infantile spasms	Electroencephalogram (EEG)—cessation of hypsarrhythmia	Video/electroencephalogram (EEG): ClinRO	Sabril (vigabatrin) <i>August 21, 2009</i>
		Complete cessation of seizures	Diary: ObsRO	
Seizure disorder: Lennox-Gastaut syndrome (LGS)	Patients 2 years of age and older with LGS	<ul style="list-style-type: none"> Drop seizure frequency (atonic, tonic, or tonic-clonic) Total seizure frequency (drop and non-drop seizures) 	Diary: PRO and/or ObsRO as appropriate	Epidiolex (cannabidiol) <i>June 25, 2018</i>
		Global impression of change	Subject/Caregiver Global Impression of Change: PRO and/or ObsRO as appropriate	
Seizure disorder: Lennox-Gastaut Syndrome (LGS)	Pediatric (2 years and up) and adult patients with LGS	Seizure frequency	Diary: PRO and/or ObsRO as appropriate	1. Onfi (clobazam) <i>October 21, 2011</i> 2. Banzel (rufinamide) <i>November 14, 2008</i>

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DIVISION OF NEUROLOGY I AND II (DN I AND II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Seizure disorder: Partial onset seizures	Pediatric patients 4 years to less than 17 years of age with partial onset seizures with or without secondary generalization	Seizure frequency	Diary: PRO and/or ObsRO as appropriate	Lyrica (pregabalin) <i>January 4, 2010</i> <i>May 3, 2018</i>
Seizure disorder: Refractory Complex Partial Seizures	Pediatric (2 years and up) and adult patients with refractory complex partial seizures	Seizure frequency	Diary: PRO and/or ObsRO as appropriate	Sabril (vigabatrin) <i>August 21, 2009</i>
Spasticity	Adults with spasticity and pediatric patients (2 years and up) with lower limb spasticity	Muscle tone	Modified Ashworth Scale (MAS): ClinRO	Dysport (abobotulinumtoxinA) <i>April 29, 2009</i> <i>June 14, 2017</i>
Spinal muscular atrophy (SMA)	Adults and pediatric patients with SMA	Motor development	Section 2 of Hammersmith Infant Neurologic Exam (HINE-motor milestones): ClinRO	Spinraza (nusinersen) <i>December 23, 2016</i>
		Motor skills	Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND): ClinRO	
Spinal muscular atrophy (SMA) — later onset	Pediatric patients with later-onset SMA	Motor function	Hammersmith Functional Motor Scale — Expanded (HFMSE): ClinRO	Spinraza (nusinersen) <i>December 23, 2016</i> <i>May 14, 2018</i>

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DIVISION OF PSYCHIATRY (DP)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Attention deficit hyperactivity disorder (ADHD)	Patients with ADHD	Severity of ADHD for patients 13 to 55 years old	ADHD Rating Scale (ADHD-RS): ClinRO ^{1,2}	1. Mydayis (mixed salts of a single-entity amphetamine product) <i>June 20, 2017</i> 2. Vyvanse (lisdexamfetamine dimesylate) <i>February 23, 2007</i>
		Severity of ADHD in pediatric patients (13 to 17 years old)	Connor's Parent Rating Scale: ObsRO ²	
		Attentional symptoms measurement in ADHD	Permanent Product Measure of Performance (PERMP): Perfo ¹	
		Department (behavior) in ADHD	Swanson, Kotkin, Angler, M-Flynn, and Pelham (SKAMP) Department Scores: ClinRO ²	
Bipolar disorder (manic or mixed)	Adults with manic or mixed episodes associated with bipolar 1 disorder	Manic symptoms	Young Mania Rating Scale (YMRS): ClinRO ^{1,2}	1. Vraylar (cariprazine) <i>September 17, 2015</i> 2. Saphris (asenapine) <i>August 13, 2009</i>
		Global clinical impression of bipolar disorder severity	Clinical Global Impression-Bipolar Severity of Illness score: ClinRO ^{1,2}	
Bipolar disorder (depressive)	Patients 10 years of age and older with bipolar 1 disorder	Major depressive symptoms (adult)	Montgomery-Åsberg Depression Rating Scale (MADRS) version 10: ClinRO	Latuda (lurasidone hydrochloride) <i>October 28, 2010</i> <i>January 27, 2017</i> <i>March 5, 2018</i>
		Global clinical impression of bipolar disorder severity	Clinical Global Impression-Bipolar-Severity of Illness Scale: ClinRO	
		Major depressive symptoms (pediatric)	Children's Depression Rating Scale, Revised (CDRS-R): ClinRO	

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DIVISION OF PSYCHIATRY (DP) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Bipolar disorder (manic or mixed)	Adults with manic or mixed episodes associated with bipolar 1 disorder	Recurrence of mood episode	ClinRO	Abilify Maintena Kit (aripiprazole) February 28, 2013 July 27, 2017
Excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)	Adults with narcolepsy or obstructive sleep apnea	Daytime sleepiness	PRO	Sunosi (solriamfetol) March 20, 2019
		Wakefulness	Maintenance of Wakefulness Test (MWT): PerfO	
		Global impression of change of symptom severity	Patient Global Impression of Change: PRO	
Insomnia	Adults with insomnia characterized by difficulty with sleep onset and/or maintenance	Sleep latency (sleep onset)	Diary: PRO ^{1,2,3}	1. Belsomra (suvorexant) August 13, 2014 2. Rozerem (ramelteon) July 22, 2005 3. Lunesta (eszopiclone) December 15, 2004
		Wake time after sleep onset [WASO] (sleep maintenance)	Polysomnography: Biomarker ^{1,3}	
Major depressive disorder (MDD)	Adults with MDD	Major depressive symptoms	Montgomery-Åsberg Depression Rating Scale (MADRS) version 10: ClinRO ^{1,2,3}	1. Rexulti (brexpiprazole) July 10, 2015 2. Trintellix (vortioxetine) September 30, 2013 3. Viibryd (vilazodone hydrochloride) January 21, 2011 4. Pristiq (desvenlafaxine succinate) February 29, 2008 5. Cymbalta (duloxetine hydrochloride) August 3, 2004
		Major depressive symptoms	Hamilton Depression Rating Scale 24 items or 17 items: ClinRO ^{2,4,5}	

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DIVISION OF PSYCHIATRY (DP) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Major depressive disorder (MDD)	Adults with MDD	Processing speed	Digit Symbol Substitution Test (DSST): PerfO	Trintellix (vortioxetine hydrobromide) <i>September 30, 2013</i> <i>May 2, 2018</i>
Major depressive disorder (MDD)	Limited Context of Use See qualification statement for additional information	Major depressive symptoms	PRO	Qualified COA: Symptoms of Major Depressive Disorder Scale (SMDDS) Visit " Clinical Outcome Assessment (COA) Qualification Program Qualified Clinical Outcome Assessments " Website for additional information
Non-24-hour sleep-wake disorder	Adults with non-24-hour sleep wake disorder	Nighttime sleep time and daytime nap time	Diary: PRO	Hetlioz (tasimelteon) <i>January 31, 2014</i>
Parkinson's disease (PD) psychosis	Adults with hallucinations and delusions associated with PD psychosis	Severity of hallucinations and delusions	PD adapted Scale for the Assessment of Positive Symptoms (SAPS-PD) hallucinations and delusions: ClinRO	Nuplazid (pimavanserin) <i>April 29, 2016</i>
Postpartum depression (PPD)	Adults with postpartum depression	Major depressive symptoms	Hamilton Depression Rating Scale (HAM-D): ClinRO	Zulresso (brexanolone) <i>March 19, 2019</i>

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DIVISION OF PSYCHIATRY (DP) (CONTINUED)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Schizophrenia	Adults with schizophrenia	Severity of schizophrenia symptoms	Positive and Negative Syndrome Scale (PANSS): ClinRO ^{1,2,3,4,5,6}	1. Aristada (aripiprazole lauroxil) <i>October 5, 2015</i>
		Positive symptoms of psychosis	Brief Psychiatric Rating Scale derived (BPRSd): ClinRO ^{3,5}	2. Vraylar (cariprazine) <i>September 17, 2015</i> <i>November 9, 2017</i>
		Global clinical impression of severity	Clinical Global Impression-Severity: ClinRO ^{2,3}	3. Latuda (lurasidone hydrochloride) <i>October 28, 2010</i> <i>January 27, 2017*</i>
		Personal and social functioning	Personal and Social Performance (PSP) scale: ClinRO ⁶	4. Saphris (asenapine) <i>August 13, 2009</i>
		Relapse of psychosis	ClinRO ^{2,7}	5. Fanapt (iloperidone) <i>May 6, 2009</i>
Tardive dyskinesia	Adults with TD	Involuntary movements associated with TD	Abnormal Involuntary Movement Scale (AIMS): ClinRO	6. Invega (paliperidone) <i>December 19, 2006</i>
				7. Invega Sustenna (paliperidone palmitate) <i>December 20, 2017</i>
				1. Ingrezza (valbenazine) <i>April 11, 2017</i>
				2. Austedo (deutetrabenazine) <i>August 30, 2017</i>

*Latuda [efficacy supplement] is approved for adults and adolescents (13 to 17 years) with schizophrenia.

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DIVISION OF ANESTHESIOLOGY, ADDICTION MEDICINE AND PAIN MEDICINE (DAAP)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Alcoholism	Adult patients who are alcohol-dependent	Attaining and maintaining abstinence or low risk drinking (e.g., frequency of alcohol consumption, quantity of alcohol consumed, and laboratory measure)	Composite <ul style="list-style-type: none"> Diary: PRO Laboratory confirmation: Biomarker 	Campral (acamprosate calcium) <i>July 29, 2004</i>
Opioid withdrawal	Adult patients with opioid withdrawal symptoms to facilitate opioid discontinuation	Opioid withdrawal symptoms	Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop) total score: PRO	Lucemyra (lofexidine) <i>May 16, 2018</i>
Pain (acute)	Patients with acute pain	Pain intensity	Numerical pain rating scale or visual analog scale: PRO	Nucynta (tapentadol hydrochloride) <i>November 20, 2008</i>
Pain (chronic)	Patients with chronic pain	Pain intensity	Numerical pain rating scale or visual analog scale: PRO	Prialt (ziconotide acetate intrathecal infusion) <i>December 28, 2004</i>
Pain (neuropathic)	Patients with neuropathic pain	Pain intensity	Numerical pain rating scale or visual analog scale: PRO	1. Qutenza (capsaicin 8% patch) <i>November 16, 2009</i> 2. Lyrica (pregabalin) <i>December 30, 2004</i>
Postsurgical local analgesia	Adults who require postsurgical local and regional analgesia	Pain intensity	Numerical pain rating scale or visual analog scale: PRO	Exparel (bupivacaine liposome) <i>October 28, 2011</i> <i>April 6, 2018</i>
Smoking cessation	Current smokers	Abstinence	Composite <ul style="list-style-type: none"> Patient-reported abstinence: PRO Laboratory measure: Biomarker 	Chantix (varenicline tartrate) <i>May 10, 2006</i>

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OFFICE OF ONCOLOGIC DISEASES (OOD)

DIVISION OF ONCOLOGY I (DO I)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/Qualification Link
Prostate cancer (Metastatic castration-resistant)	Adult patients with metastatic castration-resistant prostate cancer	Pain intensity	Brief Pain Inventory Item #3—Short Form: PRO	Zytiga (abiraterone acetate) <i>April 28, 2011</i>
Prostate cancer (Non-metastatic castration-resistant)	Patients with non-metastatic castration-resistant prostate cancer	Symptomatic progression	Composite: ClinRO	Erleada (apalutamide) <i>February 14, 2018</i>

DIVISION OF ONCOLOGY II (DO II)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/Qualification Link
Metastatic non-small cell lung cancer (NSCLC)	Adults with NSCLC whose tumors are anaplastic lymphoma kinase (ALK)-positive	Delay in time to development or worsening of shortness of breath	European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire (EORTC QLQ C-30 / LC13): PRO	Zykadia (ceritinib) <i>May 26, 2017</i>

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DIVISION OF ONCOLOGY II (DO II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Non-small cell lung cancer (NSCLC)	Limited Context of Use See qualification statement for additional information	Overall severity of the following NSCLC symptoms: cough, pain, dyspnea, fatigue, and appetite	PRO	Qualified COA: Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ) Visit " Clinical Outcome Assessment (COA) Qualification Program Qualified Clinical Outcome Assessments " Website for additional information
Recurrent glioblastoma	Adults with recurrent glioblastoma	Discontinuation of corticosteroid use	ClinRO	Avastin (bevacizumab) <i>February 26, 2004</i> <i>December 5, 2017</i>
TSC-associated partial-onset seizures	Adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures	Seizure frequency	Diary: PRO or ObsRO , as appropriate	Afinitor Disperz (everolimus) <i>August 29, 2012</i> <i>April 10, 2018</i>

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DIVISION OF HEMATOLOGIC MALIGNANCIES I (DHM I)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Acute myeloid leukemia (AML)	Adult patients with relapsed or refractory AML and an IDH2 mutation	Transfusion dependence	ClinRO/Biomarker	Idhifa (enasidenib) <i>August 17, 2017</i>
	Adult patients with relapsed or refractory AML and an IDH1 mutation	Transfusion dependence	ClinRO/Biomarker	Tibsovo (ivosidenib) <i>July 20, 2018</i>
	Adult patients with relapsed or refractory AML with a FLT3 mutation	Transfusion dependence	ClinRO/Biomarker	Xospata (gilteritinib) <i>November 28, 2018</i>
Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Patients aged 2 years and older with blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Complete response or clinical Complete Response (CR/CRc)	ClinRO/Biomarker	Elzonris (tagraxofusp-erzs) <i>December 21, 2018</i>

DIVISION OF HEMATOLOGIC MALIGNANCIES II (DHM II)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Chronic graft versus host disease (cGVHD)	Adults with cGVHD after failure of one or more lines of systemic therapy	Patient-reported symptom bother	Lee Symptom Scale Total Score: PRO	Imbruvica (ibrutinib) <i>November 13, 2013</i> <i>August 2, 2017</i>
		Overall response rate	Modified 2005 National Institute of Health (NIH) Consensus Panel Response Criteria: ClinRO/PRO/Biomarker	

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DIVISION OF HEMATOLOGIC MALIGNANCIES II (DHM II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Chronic lymphocytic leukemia	Adult patients with CLL	Composite <ul style="list-style-type: none"> • Incidence of palpable hepatosplenomegaly • Size of lymph nodes; incidence of lymph nodes with nodularity • B symptoms evaluation (night sweats, fever, unexplained weight loss) • Laboratory measures (lymphocytes, neutrophils, platelets, histology) 	Composite <ul style="list-style-type: none"> • ClinRO • ClinRO • Laboratory measures: Biomarker(s) 	Treanda (bendamustine hydrochloride) <i>March 20, 2008</i>
Chronic lymphocytic leukemia (CLL)/Small lymphocytic leukemia (SLL)	Adults with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies	Overall response rate	2008 International Workshop for Chronic Lymphocytic Leukemia (IWCLL) guidelines or 2007 International Working Group (IWG) Revised Response Criteria for Malignant Lymphoma with modification for treatment-related lymphocytosis: ClinRO/Biomarker	Copiktra (duvelisib) <i>September 24, 2018</i>
	Adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy	Overall response rate	2008 International Workshop for Chronic Lymphocytic Leukemia (IWCLL) guidelines: ClinRO/Biomarker	Venclexta (venetoclax) <i>April 11, 2016</i> <i>June 8, 2018</i>

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DIVISION OF HEMATOLOGIC MALIGNANCIES II (DHM II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Cutaneous T-cell lymphoma (CTCL)	Adult patients with CTCL	Skin involvement	Severity Weighted Assessment Tool (SWAT) in addition to other outcomes (e.g., response duration, time to progression, time to objective response): ClinRO	Zolinza (vorinostat) <i>October 6, 2006</i>
		Physician's global assessing improvement or worsening in overall disease	7-Point Physician's Global Assessment scale: ClinRO	
Follicular lymphoma (FL)	Adults with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies	Overall response rate	2007 International Working Group Revised Response Criteria for Malignant Lymphoma: ClinRO/ Biomarker	1. Aliqopa (copanlisib) <i>September 14, 2017</i> 2. Copiktra (duvelisib) <i>September 24, 2018</i>
Mucositis	Adult patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support	Incidence and severity of oral mucositis (e.g., soreness/erythema, ulcers, oral intake tolerability)	World Health Organization Oral Mucositis Scale: ClinRO	Kepivance (palifermin) <i>December 15, 2004</i>
Multiple myeloma	Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors	Skeletal-related events: <ul style="list-style-type: none"> • Pathologic fracture • Radiation therapy to bone • Surgery to bone • Spinal cord compression 	ClinRO	Xgeva (denosumab) <i>June 1, 2010</i> <i>January 4, 2018</i>

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DIVISION OF HEMATOLOGIC MALIGNANCIES II (DHM II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Mycosis fungoides (MF) or Sézary syndrome	Adults with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy	Overall response rate based on global composite response criteria: <ul style="list-style-type: none"> • modified Severity Weighted Assessment Tool (mSWAT) • Skin photographs • Central flow cytometry • Computed tomography 	Composite: <ul style="list-style-type: none"> • ClinRO • ClinRO • Biomarker • Biomarker 	Poteligeo (mogamulizumab-kpkc) <i>August 8, 2018</i>
Mycosis fungoides (MF)	Adults with CD30-expressing mycosis fungoides requiring systemic therapy	Global response: <ul style="list-style-type: none"> • Skin evaluations per modified severity-weighted assessment tool (mSWAT) • Nodal and visceral radiographic assessment • Detection of circulating Sézary cells 	Composite: <ul style="list-style-type: none"> • ClinRO • Biomarker • Biomarker 	Adcetris (brentuximab vedotin) <i>August 19, 2011</i> <i>November 9, 2017</i>
Primary cutaneous anaplastic large cell lymphoma (pcALCL)	Adults with pcALCL requiring systemic therapy	Global response: <ul style="list-style-type: none"> • Skin evaluations per modified severity-weighted assessment tool (mSWAT) • Nodal and visceral radiographic assessment 	Composite: <ul style="list-style-type: none"> • ClinRO • Biomarker 	Adcetris (brentuximab vedotin) <i>August 19, 2011</i> <i>November 9, 2017</i>
Primary mediastinal large B-Cell lymphoma	Adults with relapsed or refractory PMBCL	Overall response rate	2007 International Working Group Revised Response Criteria for Malignant Lymphoma: ClinRO/Biomarker	Keytruda (pembrolizumab) <i>September 4, 2014</i> <i>June 19, 2018</i>

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DIVISION OF HEMATOLOGIC MALIGNANCIES II (DHM II) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Systemic mastocytosis	Adult patients with systemic mastocytosis associated with hematological neoplasm	Assessment of complete remission (CR) response	2013 International Working Group—Myeloproliferative Neoplasms Research and Treatment—European Competence Network on Mastocytosis (IWG-MRT-ECNM): ClinRO	Rydapt (midostaurin) <i>April 28, 2017</i>

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OFFICE OF RARE DISEASES, PEDIATRICS, UROLOGY AND REPRODUCTIVE MEDICINE (ORPURM)

DIVISION OF RARE DISEASES AND MEDICAL GENETICS (DRDMG)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Hypophosphatasia (HPP)	Patients with perinatal/ infantile and juvenile-onset HPP	Assessment of gait	Modified Performance Oriented Mobility Assessment-Gait (MPOMA-G): PerfO	Strensiq (asfotase alfa) <i>October 23, 2015</i>
		Walking distance	6 Minute Walk Test (6MWT): PerfO	
		Assess skeletal burden in HPP	Radiographic Global Impression of Change (RGI-C): ClinRO	
Mucopolysaccharidosis I (MPS I) (Hurler and Hurler- Scheie forms of MPS I)	Pediatric and/or adult patients with MPS I	Walking distance	6 Minute Walk Test (6MWT): PerfO	Aldurazyme (laronidase) <i>April 30, 2003</i>
Mucopolysaccharidosis II (MPS II) (Hunter syndrome)	Pediatric and/or adult patients with MPS II	Walking distance	6 Minute Walk Test (6MWT): PerfO	Elaprase (idursulfase) <i>July 24, 2006</i>
Mucopolysaccharidosis IVA (MPS IVA) (Morquio A syndrome)	Pediatric and/or adult patients with MPS IVA	Walking distance	6 Minute Walk Test (6MWT): PerfO	Vimizim (elosulfase) <i>February 14, 2014</i>
		Stair-climbing capacity	3 Minute Stair Climb Test: PerfO	
Mucopolysaccharidosis VI (MPS VI) (MaroteauxLamy syndrome)	Pediatric and/or adult patients with MPS VI	Walking distance	12-Minute Walk Test: PerfO	Naglazyme (galsulfase) <i>May 31, 2005</i>
		Stair-climbing capacity	3-Minute Stair Climb Test: PerfO	

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DIVISION OF RARE DISEASES AND MEDICAL GENETICS (DRDMG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Mucopolysaccharidosis VII (MPS VII, Sly syndrome)	Pediatric and/or adult patients with MPS VII	Walking distance	6 Minute Walk Test (6MWT): PerfO	Mepsevii (vestronidase alfa) <i>November 15, 2017</i>
Neuronal ceroid lipofuscinosis type 2 (CLN2)	Symptomatic pediatric patients 3 years of age and older with late infantile CLN2	Measure of motor related functioning/mobility	CLN2 Clinical Rating Scale (motor domain): ClinRO	Brineura (cerlinponase alfa) <i>April 27, 2017</i>
Pompe disease, late-onset	Patients with Pompe disease, late-onset	Walking distance	6-Minute Walk Test: PerfO	Lumizyme (alglucosidase alfa) <i>May 24, 2010</i>
Urea cycle disorder (UCD)	Patients 2 months to less than 2 years with UCD	Composite <ul style="list-style-type: none"> • Signs and symptoms of hyperammonemia • Venous ammonia value 	Composite: <ul style="list-style-type: none"> • ClinRO • Biomarker 	Ravicti (glycerol phenylbutyrate) <i>April 28, 2017</i>

DIVISION OF UROLOGY, OBSTETRICS, AND GYNECOLOGY (DUOG)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Benign prostatic hyperplasia (BPH)	Adults with BPH	BPH symptoms severity (irritative and obstructive symptoms)	International prostate symptom score (IPSS): PRO	1. Rapaflo (silodocin) <i>October 8, 2008</i> 2. Uroxatral (alfuzosin hydrochloride) <i>June 12, 2003</i>

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DIVISION OF UROLOGY, OBSTETRICS, AND GYNECOLOGY (DUOG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Contraception	Prevention of pregnancy in female patients with reproductive potential	Pregnancy rate	ClinRO ^{1,2}	1. Annovera (segesterone acetate and ethinyl estradiol) <i>August 10, 2018</i>
		Return to fertility	Diary: PRO ¹	2. Liletta (levonorgestrel) <i>February 26, 2015</i> <i>October 15, 2018</i>
Endometriosis	Females with moderate-to-severe pain associated with endometriosis	Dysmenorrhea pain	Endometriosis Daily Pain Impact Scale: PRO	Orilissa (elagolix) <i>July 23, 2018</i>
		Non-menstrual pelvic pain		
		Dyspareunia		
		Worst endometriosis pain	Numerical pain rating scale: PRO	
Erectile dysfunction	Adult men diagnosed with erectile dysfunction	Erectile function	Erectile function domain of the International Index of Erectile Function (IIEF): PRO	1. Stendra (avanafil) <i>April 27, 2012</i>
		Attainment and maintenance of erection	Sexual Encounter Profile (SEP) diary: PRO	2. Cialis (tadalafil) <i>November 21, 2003</i> 3. Levitra (vardenafil hydrochloride) <i>August 19, 2003</i>

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DIVISION OF UROLOGY, OBSTETRICS, AND GYNECOLOGY (DUOG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Hypoactive sexual desire disorder (Female)	Adult premenopausal women with acquired, generalized hypoactive sexual desire disorder	Sexual satisfaction	Satisfying sexual events (SSEs): PRO ¹	1. Addyi (flibanserin) <i>August 18, 2015</i> 2. Vyleesi (bremelanotide) <i>June 21, 2019</i>
			Female Sexual Encounter Profile-Revised (FSEP-R) Question 10 Satisfying Sexual Event (SSE): PRO ²	
		Sexual desire	Sexual desire from e-Diary: PRO ¹	
			Female Sexual Function Index Desire Domain (FSFI Questions 1 & 2): PRO ^{1,2}	
		Sexually-related distress	Female Sexual Distress Scale—Revised (FSDS-R): PRO ¹	
			Female Sexual Distress Scale — Desire/Arousal/Orgasm Question 13 (FSDS-DAO Q13): PRO ²	
Nocturia	Adults with nocturnal polyuria who waken at least 2 times per night to void	Nocturia episodes	Nocturic episodes: PRO	Noctiva (desmopressin acetate) <i>March 3, 2017</i>
		Nighttime urination bother	Impact of Nighttime Urination (INTU) questionnaire: PRO	

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DIVISION OF UROLOGY, OBSTETRICS, AND GYNECOLOGY (DUOG) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Overactive bladder	Patients with overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	Incontinence episodes, urinary frequency and urinary void volume	Voiding diary: PRO	1. Myrbetriq (mirabegron) <i>June 28, 2012</i> <i>April 27, 2018</i> 2. Toviaz (fesoterodine) <i>October 31, 2008</i> 3. Enablex (darifenacin hydrobromide) <i>December 22, 2004</i> 4. Vesicare (solifenacin succinate) <i>November 19, 2004</i>
Vasomotor symptoms (VMS)	Postmenopausal women with moderate-to-severe VMS due to menopause	Frequency of VMS (hot flashes/flushes)	Diary: PRO	Duavee (conjugated estrogens/bazedoxifene) <i>October 3, 2013</i>
		Severity of VMS (hot flashes/flushes)	Daily severity score: PRO	
Vulvar and vaginal atrophy (VVA)	Postmenopausal women with moderate-to-severe symptoms of VVA due to menopause	Symptoms of vulvar and vaginal atrophy (e.g., vaginal dryness, dyspareunia, vaginal irritation/itching)	Diary: PRO	Osphena (ospemifene) <i>February 26, 2013</i>

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OFFICE OF SPECIALTY MEDICINE (OSM)

DIVISION OF OPHTHALMOLOGY (DO)				
Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/Qualification Link
Allergic conjunctivitis (itching associated with allergic conjunctivitis)	Pediatric and adult patients with itching associated with allergic conjunctivitis	Ocular itching severity	5-point itching severity numerical rating scale with half unit increments: PRO	<ol style="list-style-type: none"> 1. Lastacraft (alcaftadine) <i>July 28, 2010</i> 2. Bepreve (bepotastine besilate) <i>September 8, 2009</i> 3. Elestat (epinastine) <i>October 16, 2003</i>
Bacterial conjunctivitis	Pediatric and adult patients with bacterial conjunctivitis along with other key efficacy measures (e.g., microbiology)	Clinical resolution based on absence of all three clinical signs (e.g., ocular discharge, bulbar conjunctival injection, and palpebral conjunctival injection)	ClinRO	Besivance (besifloxacin hydrochloride) <i>May 28, 2009</i>
		Microbiological eradication	Laboratory measure: Biomarker	
Cataract surgery or intraocular lens replacement	Patients undergoing ocular surgery	Absence of post-surgical ocular pain/discomfort	Visual analog scale (VAS): PRO	Omidria (phenylephrine and ketorolac intraocular solution) <i>May 30, 2014</i> <i>December 8, 2017</i>
		Intraoperative miosis	Pupil diameter: ClinRO	
Diabetic retinopathy (DR)	Adults with diabetic retinopathy	Severity of retinopathy	Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scores (ETDRS-DRSS): ClinRO	Lucentis (ranibizumab) <i>April 15, 2017</i>

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DIVISION OF OPHTHALMOLOGY (DO) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Dry eye disease (DED)	Adults with eye dryness	Symptoms of DED: Extent of eye dryness	Eye Dryness Score (EDS) rated by a Visual Analogue Scale (VAS): PRO	Xiidra (lifitegrast ophthalmic solution) <i>July 11, 2016</i>
		Signs of DED	Inferior fluorescein corneal staining score (ICSS): ClinRO	
Myopic choroidal neovascularization (mCNV)	Adults with high myopia and choroidal neovascularization	Best Corrected Visual Acuity (BCVA)	BCVA Assessment: PerfO	Lucentis (ranibizumab) <i>January 5, 2017</i>
Neovascular (wet) age-related macular degeneration	Adults with age-related macular degeneration	Best Corrected Visual Acuity (BCVA)	BCVA assessment: PerfO	1. Eylea (afibercept) <i>November 18, 2011</i> 2. Macugen (pegaptanib sodium) <i>September 17, 2004</i> 3. Lucentis (ranibizumab) <i>June 30, 2006</i>
Neurotrophic keratitis	Patients with neurotrophic keratitis	Absence of staining of the corneal lesion	ClinRO	Oxervate (cenegermin-bkbj) <i>August 22, 2018</i>
Ocular inflammation and pain associated with ocular surgery	Adults undergoing ocular surgery	Absence of post-surgical ocular inflammation	Slit lamp evaluation and anterior chamber cell/flare grade score: ClinRO	1. Durezol (difluprednate) <i>June 23, 2008</i> 2. Nevanac (nepafenac) <i>August 19, 2005</i>
		Absence of post-surgical ocular pain/discomfort	Visual Analog Scale (VAS) and/or 6-point numeric pain rating scale: PRO	
Ophthalmic surgery aid	Patients undergoing ophthalmic surgical procedures	Anterior lens capsule staining	Biomechanics: ClinRO	VisionBlue (trypan blue) <i>December 16, 2004</i>

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DIVISION OF OPHTHALMOLOGY (DO) (CONTINUED)

Disease/Condition	COA Context of Use	Concept	COA Tool & Type	Drug Name/Approval Date/ Qualification Link
Vitreomacular adhesion	Adults with symptomatic vitreomacular adhesion	Nonsurgical vitreomacular adhesion resolution	Biomicroscopy using 4-point scale: ClinRO	Jetrea (ocriplasmin) <i>October 17, 2012</i>
		Best Corrected Visual Acuity (BCVA)	BCVA assessment: Perf0	

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10903 New Hampshire Avenue
Silver Spring, Maryland 20993
www.fda.gov