CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

RT 1,2 or 3	Drug Name	Review Reason	FDA-Approved Indication(s)	Utilization Management Recommendation	Product Comparison	P & T Formulary decision pending Strategy Development Committee review
1	brodalumab (Siliq®)	New drug	Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.	There is significant potential for inappropriate use and utilization management should be considered for the following reason(s): Siliq is the only biologic agent for the treatment of plaque psoriasis with a black box warning for suicidal ideation and behavior. Siliq is FDA approved as a second line agent after failure or inadequate response to other systemic therapies. Recommended utilization management tool of Prior Authorization.	CPAC score: 66 vs. Stelara (ustekinumab) - Modest benefits over current therapies CPAC score: 54 vs. Taltz (ixekizumab) - Equal therapeutic outcomes anticipated Equal therapeutic outcomes are anticipated for Taltz and Siliq; therefore, it would be appropriate to provide equal access to both Taltz and Siliq. It would not be clinically appropriate to require a trial of Siliq prior to Taltz due to the black box warning for suicidal ideation associated with Siliq. Modest therapeutic outcomes are anticipated for Siliq over Stelara for	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

					the treatment of plaque psoriasis; therefore, it would not be clinically appropriate to require a trial of Stelara prior to Siliq.	
1	crisaborole (Eucrisa®)	New drug	A phosphodiesterase 4 inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.	There is not significant potential for inappropriate use.	CPAC score: 52 vs. pimecrolimus (Elidel) – Equal therapeutic outcomes anticipated. Equal therapeutic outcomes are anticipated for crisaborole and pimecrolimus, therefore it would be appropriate to provide equal access to both or to require a trial of one before the other. It would be clinically appropriate to require a trial of a low to medium potency topical corticosteroid prior to initiation of Eucrisa.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.
1	deflazacot (Emflaza®)	New drug	Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.	There is significant potential for inappropriate use and utilization management should be considered for the following reason(s):	CPAC score: 53 vs. Prednisone – Equal therapeutic outcomes anticipated	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement

				To prevent inappropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes. Emflaza is an oral corticosteroid and can potentially be used off-label in conditions where corticosteroids are indicated; To ensure that Emflaza is used only in the treatment of Duchenne muscular dystrophy. Recommended utilization management tool of Prior Authorization.	Equal therapeutic outcomes are anticipated for Emflaza and prednisone; therefore, it would be appropriate to provide equal access to both or to require a trial of one before the other.	and is determined by SDC after the product has launched.
1	nusinersen (Spinraza®)	New drug	Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.	There is significant potential for inappropriate use and utilization management in the form of a prior authorization is recommended.	Only available first line therapy for spinal muscular atrophy (Not scored) There are no clinically appropriate therapeutic alternatives.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.
1	plecanatide (Trulance®)	New drug	The treatment of chronic idiopathic constipation (CIC) in adult patients.	There is significant potential for inappropriate use and utilization management should be considered for the following reason(s):	CPAC score: 53 vs. Linzess Equal therapeutic outcomes anticipated Equal therapeutic outcomes are anticipated for Trulance and Linzess; therefore, it	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

				i) To prevent inappropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes (1) Trulance is being evaluated in clinical trials for irritable bowel syndrome characterized by constipation (IBS-C) Recommended utilization management tool of Prior Authorization.	would be appropriate to provide equal access to both or to require a trial of one before the other. It would be clinically appropriate to require a trial of two laxative agents (bulk-forming, emollients, osmotic and/or stimulant) prior to the initiation of Trulance.	and is determined by SDC after the product has launched.
1	racaparib (Rubraca®)	Expedited abbreviated review of Centers for Medicare & Medicaid Services protected class drugs.	For the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca. This indication is approved under accelerated approval based on objective	There is significant potential for inappropriate use and utilization management in the form of a prior authorization is recommended.	Only available third line therapy for ovarian cancer. It would be clinically appropriate to require a trial of two or more prior chemotherapies, including platinum agents.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.

			response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.			
2	Ibrutinib (Imbruvica®)	Expedited abbreviated review of Centers for Medicare & Medicaid Services protected class drugs.	A kinase inhibitor indicated for the treatment of patients with: • Mantle cell lymphoma (MCL) who have received at least one prior therapy • Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma(SLL) • Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma(SLL) with 17p deletion	There is significant potential for inappropriate use and utilization management should be considered for the following reason(s): To prevent inappropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes. Imbruvica is being evaluated in clinical trials for many other uses, including follicular lymphoma, multiple myeloma, refractory/recurrent primary central nervous system lymphoma, refractory/recurrent secondary central nervous system lymphoma, non-small cell lung	Only agent with this indication.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

			• Waldenström's macroglobulinemia (WM) • Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.	cancer, and advanced carcinoid and pancreatic neuroendocrine tumors. Recommended utilization management tool of Prior Authorization. It would be clinically appropriate to require a trial of rituximab-containing regimen prior to approval of Imbruvica for MZL.		
2	oxymetazoline (Rhofade®)	Abbreviated review of new dosage forms of existing agents that are approved for a new indication or use.	Indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.	There is not significant potential for inappropriate use. If papules or pustules are present, it would be clinically appropriate to require a trial of or concomitant treatment with any of the following agents: topical metronidazole *(preferred)*, oral doxycycline *(preferred)* or Finacea *(non-preferred)*	Equal therapeutic outcomes are anticipated for Rhofade and Mirvaso; therefore, it would be appropriate to provide equal access to both or to require a trial of one before the other.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

2	ranibizumab (Lucentis®)	Abbreviated review of new dosage forms of existing agents that are approved for a new indication or use.	A vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy in patients with DME • Myopic Choroidal Neovascularization (mCNV)	There is significant potential for inappropriate use and utilization management should be considered for the following reason(s): To prevent inappropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes. Lucentis is currently being evaluated in clinical trials for many uses, including retinoblastoma, telangiectasia, polypoidal choroidal vasculopathy, port wine stain birthmark, and pigment epithelial detachment. Recommended utilization management tool of Prior Authorization. It would not be clinically appropriate to require a trial of Avastin prior to initiation of Lucentis for mCNV.	N/A	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

2	ustekinumab (Stelara®)	Abbreviated review of new dosage forms of existing agents that are approved for a new indication or use.	Treatment of adult patients with: moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy; active psoriatic arthritis (PsA), alone or in combination with methotrexate; moderately to severely active Crohn's disease (CD) who have 1) failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or 2) failed or were intolerant to treatment with one or more TNF blockers	There is significant potential for inappropriate use and utilization management should be considered for the following reason(s): To ensure appropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes. FDA indication is approved for moderate to severe Crohn's Disease who have: 1) failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or 2)failed or were intolerant to treatment with one or more TNF blockers. Recommended utilization management tool of Prior Authorization.	Approve proposed utilization guidelines.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement and is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
SECOND QUARTER 2017 NEW DRUG ARRIVALS SUMMARY

* Review Type Descriptions 1,2 or 3

Review Type 1 - New Drug Review is normally scheduled for new chemical or biologic agents which are administered orally or by selfadministered injection.

Review Type 2 - New Indication Review is a less inclusive review for products which are generally new dosage forms of existing agents but are approved for a new use. This type of review includes a PA guideline and an overall review. Generally these are already existing drugs with a prior authorization that have a new FDA approved indication.

Review Type 3 - Expedited abbreviated review of Centers for Medicare & Medicaid Services protected class drugs (anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants).