CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

RT 1,2, 3,5	Drug Name	Review Reason	FDA-Approved Indication(s)	Utilization Management Recommendation	Product Comparison	P & T Formulary Decision Pending Strategy Development Committee Review
1	Brigatinib (Alunbrig™)	New Drug	Alunbrig is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 58 vs. Zykadia (ceritinib) – Equal therapeutic outcomes anticipated. CPAC score: 57 vs Alecensa (alectinib) – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Deutetrabenazine (Austedo™)	New Drug	Austedo is indicated for the treatment of chorea associated with Huntington's disease.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 58 vs. Xenazine – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Cerliponase alfa (Brineura™)	New Drug	Brineura is indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Brineura was not scored because it is the only FDA-approved therapeutic option to slow the loss of ambulation in	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

			infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.		symptomatic pediatric patients with CLN2.	determined by SDC after the product has launched.
1	Dupilumab (Dupixent®)	New Drug	Dupixent is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 59 vs. systemic cyclosporine (off-label) – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Valbenazine (Ingrezza™)	New Drug	Ingrezza is indicated for the treatment of adults with tardive dyskinesia.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 59 vs. Austedo – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

						after the product has launched.
1	Ribociclib (Kisqali®)	New Drug	Kisqali is indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.	There is not significant potential for inappropriate use.	CPAC score: 44 vs. Ibrance – May be used under unique circumstances.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Ocrelizumab (Ocrevus™)	New Drug	Ocrevus is indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis (MS).	There is not significant potential for inappropriate use.	Relapsing-remitting MS (RRMS): CPAC score: 69 vs. Rebif – Modest benefits over current therapies. CPAC score: 47 vs. Tecfidera – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

					Primary-progressive MS (PPMS): Ocrevus was not scored for PPMS because it is the only FDA-approved therapeutic option.	
1	House dust mite (Dermatophagoides farinae and Dermatophagoides pteronyssinus) allergen extract (Odactra™)	New Drug	Odactra is indicated as immunotherapy for house dust mite-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts in adults 18 years through 65 years of age.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 57 vs. subcutaneous immunotherapy (SCIT) (allergen extract of Standardized Mite Dermatophagoides farinae and Dermatophagoides pteronyssinus) – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Edaravone (Radicava™)	New Drug	Radicava is indicated for the treatment of	There is significant potential for inappropriate use, and utilization	Not applicable.	Approval of the Utilization Management

			amyotrophic lateral sclerosis (ALS).	management in the form of a prior authorization is recommended.		recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Midostaurin (Rydapt®)	New Drug	Rydapt is indicated for the treatment of newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation; and treatment of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	AML: Rydapt was not scored as it is the only available therapy for FLT3 mutation positive disease. ASM: CPAC score: 69 vs. Gleevec – Modest benefits over current therapies.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

1	Naldemedine (Symproic®)	New Drug	Symproic is indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 57 vs. Movantik – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Abaloparatide (Tymlos®)	New Drug	Tymlos is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 52 vs. Forteo – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Safinamide (Xadago®)	New Drug	Xadago is indicated as adjunctive treatment to levodopa/carbidopa in patients with	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 56 vs. Comtan – Equal therapeutic outcomes anticipated.	Approval of the Utilization Management recommendation and prior authorization policy. The final

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

			Parkinson's disease experiencing "off" episodes.		CPAC score: 56 vs. Azilect – Equal therapeutic outcomes anticipated.	formulary placement is determined by SDC after the product has launched.
1	Telotristat ethyl (Xermelo™)	New Drug	Xermelo is indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Xermelo was not scored because it is the only FDA-approved second-line therapeutic option for carcinoid syndrome diarrhea.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
1	Niraparib (Zejula™)	New Drug	Zejula is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	CPAC score: 68 vs. Rubraca – Modest benefits over current therapies.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

2	Ledipasvir-sofosbuvir (Harvoni®)	New Indication	Harvoni is indicated for the treatment of pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
2	Palbociclib (Ibrance®)	New Indication	"Letrozole as initial endocrine-based therapy in postmenopausal women" was revised to "An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women."	There is not significant potential for inappropriate use.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
2	Ranibizumab (Lucentis®)	New Indication	Lucentis is indicated for the treatment of patients with diabetic retinopathy.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

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CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

2	Desmopressin acetate nasal spray (Noctiva™)	New Indication	Noctiva is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	It would not be clinically appropriate to require a trial of any other desmopressin formulation prior to Noctiva. It would not be clinically appropriate to require a trial of Noctiva prior to any other desmopressin formulation as the strengths of these products differ.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
2	Infliximab-abda (Renflexis™)	New Indication (New Biosimilar)	Renflexis is indicated for all of the same uses as Remicade except for pediatric ulcerative colitis.	There is not significant potential for inappropriate use relative to Remicade.	Equal therapeutic outcomes are anticipated for Renflexis and Remicade; 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 is determined by SDC after the product has launched.
2	Lenalidomide (Revlimid®)	New Indication	Revlimid is indicated for the treatment of patients with multiple myeloma as maintenance following	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	It would not be clinically appropriate to require a trial of Velcade (NCCN category 2A recommendation) prior to initiation of	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

			autologous hematopoietic stem cell transplantation (auto-HSCT).		Revlimid (NCCN category 1 recommendation) for maintenance therapy following auto-HSCT.	determined by SDC after the product has launched.
2	Sofosbuvir (Sovaldi®)	New Indication	Sovaldi is indicated for the treatment of chronic hepatitis C virus (HCV) in pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
2	Regorafenib (Stivarga®)	New Indication	Stivarga is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable. It is the only available second line therapy for HCC.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

2	Ombitasvir-paritaprevir-ritonavir (Technivie™)	New Indication	Technivie is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection with compensated cirrhosis.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Based on the AASLD-IDSA guidelines, it would be clinically appropriate to provide equal access to any of the following four FDA labeled drugs or to prefer any one drug over another: Technivie, Epclusa, Zepatier, and Harvoni. The AASLD-IDSA guidelines recommend against using the FDA labeled drugs Sovaldi and Olysio.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
5	Avelumab (Bavencio®)	Intravenous Chemo-therapy	Bavencio is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

			adjuvant treatment with platinum-containing chemotherapy.			
5	Durvalumab (Imfinzi™)	Intravenous Chemo-therapy	Imfinzi is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.
5	Pembrolizumab (Keytruda®)	Intravenous Chemo-therapy	Keytruda is indicated: • In combination with pemetrexed and carboplatin for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer;	There is significant potential for inappropriate use, and utilization management in the form of a prior authorization is recommended.	Not applicable.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

			• For the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy, or who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; • For the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior			

			treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.			
5	Atezolizumab (Tecentriq®)	Intravenous Chemo-therapy	Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.	There is not significant potential for inappropriate use.	It would not be clinically appropriate to require a trial of platinum-based chemotherapy prior to initiation of Tecentriq for patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-ineligible. It would be clinically appropriate to require a trial of platinum-based chemotherapy for patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-eligible.	Approval of the Utilization Management recommendation and prior authorization policy. The final formulary placement is determined by SDC after the product has launched.

CENTENE PHARMACY & THERAPEUTICS COMMITTEE
THIRD QUARTER 2017 NEW DRUG ARRIVALS SUMMARY TABLE

Review Type (RT) Descriptions 1, 2, 3, or 5

Review type 1 (RT1): New Drug Review
Full review of new chemical or biologic agents

Review type 2 (RT2): New Indication Review
Abbreviated review of new dosage forms of existing agents that are approved for a new indication or use

Review type 3 (RT3): Expedited CMS Protected Class Drug Review
Expedited abbreviated review of Centers for Medicare & Medicaid Services protected class drugs (anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants)

Review type 5 (RT5): Abbreviated Reviews for Intravenous Chemotherapy Agents
Abbreviated review for intravenous chemotherapy agents which are usually covered under the medical benefit