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

Drug Name	Review Type 1,2,3 or 4 *	Indication(s)	Recommendation(s)
Intrarosa	1	Intrarosa is a steroid indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.	There is not significant potential for inappropriate use. CPAC score: 60 vs. Premarin Vaginal Cream - Equal therapeutic outcomes anticipated Equal therapeutic outcomes are anticipated for Intrarosa and Premarin Vaginal Cream 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 vaginal lubricants or vaginal moisturizers prior to initiation of Intrarosa.
Zinplava	1	Zinplava is indicated to reduce recurrence of *Clostridium difficile* infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.	There is significant potential for inappropriate use and utilization management should be considered for the following reasons: To ensure that Zinplava is not be used for routine prophylaxis in patients without the risk of *C. difficile* recurrence; To ensure that Zinplava is used concomitantly with an antibacterial agent. Recommended utilization management tool is prior authorization.
Amjevita	2	Approved as a biosimilar to Humira (adalimumab), Amjevita is a tumor necrosis factor (TNF) blocker indicated for the treatment of: Rheumatoid arthritis (RA), Juvenile	There is significant potential for inappropriate use

		idiopathic arthritis (JIA), Psoriatic arthritis (PsA), Ankylosing spondylitis, Adult Crohn's disease (CD), Ulcerative colitis (UC), Plaque psoriasis (Ps).	Recommended utilization management tool is prior authorization. Equal therapeutic outcomes are anticipated for Amjevita and Humira; therefore, it would be appropriate to provide equal access to both or to require a trial of one before the other. Amjevita is not FDA approved for the following indications still protected through regulatory exclusivities: hidradenitis suppurativa (HS), JIA in patients 2-3 years of age, pediatric Crohn's disease, and uveitis (UV). Until patent exclusivities on these indications expire, a prior trial of Amjevita should not be required before coverage of Humira.
Avastin	4	Avastin is indicated for the treatment of : Metastatic colorectal cancer; Non-squamous non-small cell lung cancer, Glioblastoma, Metastatic renal cell carcinoma, Cervical cancer, Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Bonjesta	4	Bonjesta is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Bromfed DM	4	Bromfed DM is indicated for the relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Darzalex	4	Darzalex is indicated: In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma or as monotherapy, for the treatment of patients with multiple myeloma.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.

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Enbrel	4	Enbrel is approved for: Rheumatoid arthritis (RA), Polyarticular juvenile idiopathic arthritis (JIA) in patients aged 2 years or older, Psoriatic arthritis (PsA), Ankylosing spondylitis (AS), Plaque psoriasis (PsO) in patients aged 4 years or older	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Evzio	4	Evzio is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Flulaval	4	FluLaval Quadrivalent is indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluLaval Quadrivalent is approved for use in persons aged 6 months and older.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Isopto Atropine	4	Isopto Atropine is indicated for mydriasis, cycloplegia, and penalization of the healthy eye in the treatment of amblyopia.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Jardiance	4	Jardiance is indicated: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Keytruda	4	*Keytruda is indicated for:* *New indication*: Treatment of metastatic non-small cell lung cancer (NSCLC) whose tumors have high programmed death receptor-1 (PD-L1) expression [(Tumor Proportion Score (TPS) ≥50%)] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC. *Existing indications*: Treatment of unresectable or metastatic melanoma. Treatment of metastatic NSCLC.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.

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		Treatment of recurrent or metastatic head and neck squamous cell carcinoma.	
Lartuvo	4	Lartruvo is indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS).	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Ofirmev	4	Ofirmev is indicated for: Management of mild to moderate pain, Management of moderate to severe pain with adjunctive opioid analgesics, Reduction of fever.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Opdivo	4	Opdivo is indicated for: *New indication*: Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy. *Existing indications*: BRAF V600 wild-type unresectable or metastatic melanoma, as a single agent. BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent. Unresectable or metastatic melanoma, in combination with ipilimumab. Metastatic non-small cell lung cancer and progression on or after platinum-based chemotherapy. Advanced renal cell carcinoma who have received prior anti-angiogenic therapy.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Renvela	4	Renvela is a phosphate binder indicated for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease on dialysis.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Selzentry	4	Selzentry has an approved indication of treatment of CCR5-tropic HIV-1 infection in patients 2 years of age and older weighing ≥ 10 kg.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Soliqua	4	Soliqua is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Tecentriq	4	Tecentriq is indicated for the treatment of: Locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.

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		chemotherapy. Locally advanced or metastatic urothelial carcinoma with disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Metastatic non-small cell lung cancer with disease progression during or following platinum-containing chemotherapy.	
Tigecycline	4	Tigecycline is indicated in patients 18 years of age and older for: Complicated skin and skin structure infections. Complicated intra-abdominal infections. Community-acquired bacterial pneumonia.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Veltassa	4	Veltassa is indicated for the treatment of hyperkalemia.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Vemlidy	4	Vemlidy is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Vermox	4	Vermox is indicated for the treatment of patients one year of age and older with gastrointestinal infections caused by Ascaris lumbricoides (roundworm) and Trichuris trichiura (whipworm).	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.
Xultophy	4	Xultophy is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily).	There is no additional clinical review required. The Strategy Development Committee will make the formulary placement decision.

* Review Type 1,2, 3 or 4
New Drug Review (Review Type 1) is normally scheduled for new chemical or biologic agents which are administered orally or by selfadministered injection.

New Indication Review (Review Type 2) 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.
Expedited CMS Protected Class Drug Review (Review Type 3) is conducted for drugs which fall into a protected class drugs (PCD) category.

Abbreviated Review (Review Type 4) is for drug products which do not require review beyond CPAC Steering. Examples of these are
1. New dosage forms or strengths of already existing products for the same indication.
2. New drugs where we never add a prior authorization such as drugs used for the treatment of HIV.
3. Drugs that will only be used in the hospital such as a drug used to treat multi-organ failure in the ICU.
4. New indications that do not change PA criteria.
5. Drugs used only for diagnostic tests.
6. Drug used in MD office or not available in pharmacies.