Centene Pharmacy & Therapeutics Committee
New Drug Arrivals Summary 3Q18 – Survey Meeting

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

Review Type	Drug Name	FDA-Approved Indication(s)	Utilization Management Recommendation	Product Comparison
RT1	burosumab-twza (Crysvita®)	Crysvita is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization. Opportunity exists to obtain clinically significant medical or laboratory information necessary to determine appropriate use of the medication.	CPAC score: 69 vs. calcitriol plus oral phosphate agent – Modest benefits over current therapies
RT1	fostamatinib disodium hexahydrate (Tavalisse®)	Tavalisse is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization. Opportunity exists to obtain clinically significant medical or laboratory information necessary to determine appropriate use of Tavalisse.	CPAC score: 39 vs Nplate – May be used under unique circumstances CPAC score 40 vs Promacta – May be used under unique circumstances
RT1	tildrakizumab-asmn (Ilumya®)	Ilumya is indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization. Opportunity exists to obtain clinically significant medical or laboratory information necessary to determine appropriate use of the medication.	CPAC score: 43 vs. Tremfya – May be used under unique circumstances
RT2	everolimus (Afinitor Disperz®)	Afinitor Disperz is indicated for the adjunctive treatment of	There is not significant potential for inappropriate use. Afinitor Disperz currently requires a PA; recommend to maintain PA status.	Only available therapy for disease or condition

		adult and pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures.		
RT2	osimertinib (Tagrisso ®)	Tagrisso is the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization. Opportunity exists to obtain clinically significant medical or laboratory information necessary to determine appropriate use of the medication.	It would be clinically appropriate to provide equal access to Tagrisso and the other EGFR TKIs (e.g., Gilotrif, Iressa, and Tarceva), or require a trial of one before the others for metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations.
RT2	rucaparib (Rubraca®)	Rubraca is indicated fFor 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 should be considered in the form of prior authorization. To prevent inappropriate use of medications that have a higher potential to cause patient harm and lead to increased medical utilization compared to therapeutic alternatives.	For maintenance treatment of ovarian cancer, it would be clinically appropriate to provide equal access to Lynparza, Zejula, and Rubraca, or require a trial of one before the others.
RT2	tisagenlecleucel (Kymriah®)	Kymriah is indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization. To prevent inappropriate use of medications that have a significant potential for use that may lead to inferior or unpredictable outcomes.	It would be clinically appropriate to provide equal access to Kymriah and

		cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.		Yescarta for r/r large B-cell lymphoma after two or more lines of systemic therapy. It would be clinically appropriate to require documentation of CD19-positive disease.
RT2	tolvaptan (Jynarque®)	Tolvaptan has been rebranded and now is approved to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).	There is not significant potential for inappropriate use.	Only available first or second line therapy for disease or condition.
RT2	trametinib and dabrafenib (Mekinist and Tafinlar®)	Mekinist and Tafinlar are indicated for: •Adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. •Treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization. Opportunity exists to obtain clinically significant medical or laboratory information necessary to determine appropriate use of the medication.	Anaplastic Thyroid Cancer: Only available first or second line therapy for disease or condition Melanoma: Only available first or second line therapy for disease or condition

		BRAF V600E mutation and with no satisfactory locoregional treatment options.		
RT5	nivolumab plus ipilimumab (Opdivo plus Yervoy®)	Yervoy and Opdivo are indicated as a combination therapy for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma.	There is not significant potential for inappropriate use. Requiring utilization management to prevent off-label use would be clinically appropriate. Opdivo and Yervoy currently require PA; recommend maintaining PA status.	Not applicable