RT 1,2, 3,5	Drug Name Generic (Brand)	Review Reason	FDA-Approved Indication(s)	Utilization Management Recommendation	Product Comparison
1	Acalabrutinib (Calquence®)	New Drug	Calquence is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.	There is significant potential for inappropriate use and utilization management should be consideredin the form of prior authorization.	Equal therapeutic outcomes anticipated.
1	Benznidazole	New Drug	Benznidazole is indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi (T. cruzi)*. This indication was approved under accelerated approval based on the number of treated patients who became Immunoglobulin G (IgG) antibody negative against the recombinant antigens of *T. cruzi*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.	There is not a significant potential for inappropriate use. It would be clinically appropriate to limit the quantity of benznidazole for 60 days.	Only available FDA-approved first or second line therapy for disease or condition (Not scored).
1	Latanoprostene bunod (Vyzulta™)	New Drug	Vyzulta is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).	There is not significant potential for inappropriate use.	It would be clinically appropriate to provide equal access to Vyzulta, ophthalmic prostaglandin analogs, ophthalmic beta-blockers, and ophthalmic alpha-2 adrenergic agonists, or to require a trial of one before the others.
1	Letermovir (Prevymis™)	New Drug	Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization.	Equal therapeutic outcomes anticipated. Equal therapeutic outcomes are anticipated for Prevymis and Cytovene; therefore, it would be clinically appropriate to provide equal access to both or to require a trial of one before the other. Equal therapeutic outcomes are anticipated for Prevymis and Valtrex; therefore, it would be clinically appropriate to provide equal access to both or to require a trial of one before the other.
1	Secnidazole (Solosec™)	New Drug	Solosec is indicated for the treatment of bacterial vaginosis (BV) in adult women.	There is not significant potential for inappropriate use. It would be clinically appropriate to limit the quantity of Solosec to 1 packet/14 days	Equal therapeutic outcomes anticipated It would be clinically appropriate to provide equal access to Solosec, metronidazole (oral and vaginal), clindamycin (oral and vaginal), and tinidazole, or to require a trial of one before the others. The aforementioned agents are recommended by the CDC and indicated for the treatment of BV.

					Comparative literature suggests that clinical cure rates are similar among the agents listed above
1	Alectinib (Alecensa ™)	New Drug		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.	As first-line systemic therapy, it would be clinically appropriate to require a trial of Alecensa prior to Xalkori or Zykadia or to provide equal access to all three agents. As subsequent systemic therapy, it would be clinically appropriate to provide equal access to Alecensa, Xalkori and Zykadia. If subsequent specifically to ALK tyrosine kinase inhibitor therapy, it would be clinically appropriate to provide equal access to Alecensa, Xalkori, Zykadia, and Alunbrig.
2	Amantadine ER (Gocovri™)	New Indication	Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.	There is not significant potential for inappropriate use.	Equal therapeutic outcomes are anticipated for immediate-release amantadine and Gocovri; therefore, it would be clinically appropriate to provide equal access to both or to require a trial of one before the other.
2	Deutetrabenazine (Austedo™)	New Indication	Treatment of tardive dyskinesia in adults	There is significant potential for inappropriate use and utilization management should be considered in the form of prior authorization	Equal therapeutic outcomes are anticipated for Austedo and Ingrezza; therefore, it would be clinically appropriate to provide equal access to both or to require a trial of one before the other. It would be clinically appropriate to provide equal access to Austedo and drugs used off-label for tardive dyskinesia (e.g., clonazepam, amantadine, tetrabenazine, levetiracetam, and botulinum toxin); however, it would not be appropriate to require any off-label drugs prior to initiation of Austedo.
2	Eculizumab (Soliris™)	New Indication	Treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody-positive.	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 require a trial of cholinesterase inhibitors and/or immunosuppressive therapies prior to Soliris.
2	Fluticasone propionate (Xhance™)	New Indication	Treatment of nasal polyps in patients 18 years of age or older.	There is not significant potential for inappropriate use.	Equal therapeutic outcomes are anticipated for Xhance, mometasone furoate, fluticasone propionate, and budesonide nasal sprays; therefore, it would be clinically appropriate to provide equal access to all or to require a trial of one before the others. Although not clinically required, it would be appropriate to limit the quantity of Xhance to 2 devices per 30 days.

2	Vemurafenib (Zelboraf™)	New Indication	Treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation	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 not be clinically appropriate to require a trial of an interferon alfa product before Zelboraf for BRAF V600 mutation positive Erdheim-Chester disease. It would be clinically appropriate to require a trial of Zelboraf before an interferon alfa product for BRAF V600 mutation positive Erdheim-Chester disease.

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

**** Formulary placement decision for new drugs is pending Strategy Development Committee (SDC) review. Formulary placement decision made by SDC is based on the utilization management recommendation presented in this document following the approval of the P & T committee.****

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