Drug Highlight – July 2016

FDA Drug Approvals

Each month the FDA approves new medications, and below is a highlight of the most relevant new approvals and/or drugs which have the potential to impact your prescription plan. While the medications below have been evaluated and approved by the FDA, they may not enter the marketplace for several weeks or months. Therefore, pricing information for these medications is typically unavailable at the time of approval.

New Brand Approvals			
Drug Name	**Uses/Treatment**	**Pricing Information**	**Other Information**
Epclusa® (sofosbuvir and velpatasvir) oral tablet	Treatment of adult patients with chronic hepatitis C virus	AWP is $29,904 per month	• Drug Information: Epclusa is a new combination product for the treatment of chronic hepatitis C infection. It may be used to treat all known HCV genotypes and may be used in patients with compensated cirrhosis or decompensated cirrhosis (if used in combination with ribavirin). The recommended treatment regimen is once daily with or without food for three months. • Formulary Management: Considered non-preferred upon market entry. • BIC SpecialtyRx: Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network. • Control Trak: Subject to Max Dollar and Max Dose edits.
Byvalson® (nebivolol and valsartan) oral tablet	Treatment of hypertension	Pricing information not yet available	• Drug Information: Byvalson is a new combination hypertension therapy that includes a beta-adrenergic blocker and an angiotensin II receptor blocker to treat hypertension (nebivolol 5mg/valsartan 80mg). • Formulary Management: Considered non-preferred upon market entry. • Control Trak: Subject to Max Dollar and Max Dose edits.
Gonitro® (nitroglycerin) sublingual powder	For acute relief of an attack or prophylaxis of angina pectoris.	Pricing information not yet available	• Drug Information: Gonitro is a new powder formulation of nitroglycerin. It is approved to treat acute chest pain or as prophylaxis prior to activities that may cause an acute attack of chest pain. • Formulary Management: Considered non-preferred upon market entry • Control Trak: Subject to Max Dollar and Max Dose edits.
Rayaldee® (calcifediol) oral capsule	Treatment for adult patients with secondary hyperparathyroidism associated with vitamin D insufficiency.	Pricing information not yet available	• Drug Information: Rayaldee is an extended-release oral capsule used to treat adult patients with stage 3 or 4 chronic kidney disease that have secondary hyperparathyroidism and vitamin D insufficiency. It should not be given to patients in stage 5 chronic kidney disease or end-stage renal disease on dialysis. • Formulary Management: Considered non-preferred upon market entry. • Control Trak: Subject to Max Dollar and Max Dose edits.

The Clinical Care Center (CCC) is MedTrak's comprehensive clinical solution to control costs and increase adherence for our Clients and Members. The Clinical Care Center is made up of 7 Steps to Improved Outcomes: Generics Plus, Formulary Management, Member & Client Education, RightChoice, Control Trak, Best-In-Class (BIC) SpecialtyRx, and Clinical Concierge.

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Drug Recalls

Drug recalls are actions taken by drug manufacturer's to remove a product from the market. Recalls may be conducted by the manufacturer on their own initiative, by request of the FDA, or mandated by the FDA. Below is a highlight of the most relevant drug recalls.

Drug Recalls			
Drug Name	Type of Recall	Reason for Recall	Actions
Zecuity® (sumatriptan) iontophoretic transdermal system	Voluntary suspension	Teva Pharmaceuticals has temporarily suspended sales, marketing and distribution of Zecuity due to postmarketing reports of application site reactions in patients treated with Zecuity. Descriptions of the application site reactions include: severe redness, cracked skin, blistering or welts, and burns or scars where the patch was worn.	• Prescribers have been advised to discontinue prescribing of Zecuity and instruct patients to discontinue use • Health care providers and patients are encouraged to report adverse events in patients that have used Zecuity to the FDA