

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.

New Brand Approvals		
Drug Name	Uses/Treatment	Plan Impact & CCC Management Strategy
Durlaza	Reduce the risk of death and myocardial infarction in patients with chronic coronary artery disease	<ul style="list-style-type: none"> • Drug Information: Durlaza is an extended-release formulation of aspirin, indicated to reduce the risk of death and myocardial infarction in patients with chronic coronary artery disease. Durlaza should not be used in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention). • Formulary Management: Considered non-preferred • Cost (AWP): \$216 per month • Clinical Concierge: Subject to management from the Clinical Care Center due to the availability of inexpensive over-the-counter aspirin formulations • Control Trak: Subject to max dollar and max dose edits
Tresiba	Treatment of diabetes	<ul style="list-style-type: none"> • Drug Information: Tresiba is a long-acting insulin analog indicated to improve glycemic control in adults with diabetes mellitus. • Formulary Management: Not yet commercially available, but will be considered non-preferred upon market entry • Cost (AWP): Cost has not been released • Control Trak: Subject to max dollar and max dose edits
Vraylar	Treatment of schizophrenia or acute treatment of bipolar I disorder	<ul style="list-style-type: none"> • Drug Information: Vraylar is an atypical antipsychotic indicated for the treatment of schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder. • Formulary Management: Not yet commercially available, but will be considered non-preferred upon market entry • Cost (AWP): Cost has not been released • Clinical Concierge: Will be evaluated for inclusion in Step Therapy programs • Control Trak: Subject to max dollar and max dose edits

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Drug Name	Uses/Treatment	Plan Impact & CCC Management Strategy
Varubi	Prevention of delayed nausea and vomiting associated with emetogenic cancer chemotherapy	<ul style="list-style-type: none"> • Drug Information: Varubi is indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy. • Formulary Management: Considered non-preferred upon market entry. • Cost (AWP): Cost has not been released • Control Trak: Subject to max dollar and max dose edits
Lonsurf	Treatment of metastatic colorectal cancer	<ul style="list-style-type: none"> • Drug Information: Lonsurf is indicated for the treatment of patients with metastatic colorectal cancer who have previously failed other therapies. Lonsurf is administered twice daily and is dosed based on patient's weight. • Formulary Management: Considered non-preferred upon market entry • Cost (AWP): Up to \$52,549 per month and varies based on dosing • Control Trak: Subject to max dollar and max dose edits • BIC SpecialtyRx: Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network • Clinical Concierge: Subject to Prior Authorization as a specialty medication. Drug-specific and evidence-based criteria developed and applied by MedTrak's Clinical Care Center to ensure appropriate utilization.

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.