

August FAC								
Drug Name	Date Drug Cosidered by EBD	Use	Current Setup	Recommendation	EBD + EBRx Rationale	Impacted Members	Cost Details	Accept or Reject
AUSTEDO XR TAB TITRATION PACK	September 2023	Huntington's and related diseases	Not Covered	Not Covered	EBRx recommends exclusion of Austedo and Austedo XR regardless of contracting. This drug was FDA-approved for Huntington Chorea (currently cover tetrabenazine for HC) or for treatment of tardive dyskinesia. There are no head to head trials with any other drugs and was FDA approved because it improved the "AIMS dyskinesia" score. The minimal clinically important difference (MCID) is a score of 2 points different from placebo. For these reasons together with the annual cost and the ICER report that showed the drug was not cost effective (cost/QALY). Austedo annual AWP cost at max dose is \$207,736; ICER determined that to reach the willingness to pay threshold of \$150,000/year, it would need to cost \$9,200 per year, not \$207K.	0; not currently covered	WAC: \$78.68 to \$236.02 per tab	
AUSTEDO XR TAB 6MG	September 2023	Huntington's and related	Not Covered	Not Covered	See Austedo XR Tab Titration Pack (above)	0; not currently covered	WAC: \$78.68 to \$236.02 per tab	
LUMRYZ PACK	September 2023	Narcolepsy	EBRx recommends exclusion of Austedo and Austedo XR regardless of contracting. This drug was FDA-approved for Huntington Chorea (currently cover tetrabenazine for HC) or for treatment of tardive dyskinesia. There are no head to head trials with any other drugs and was FDA approved because it improved the "AIMS dyskinesia" score. The minimal clinically important difference (MCID) is a score of 2 points different from placebo. For these reasons together with the annual cost and the ICER report that showed the drug was not cost effective (cost/QALY). Austedo annual AWP cost at max dose is \$207,736; ICER determined that to reach the willingness to pay threshold of \$150,000/year, it would need to cost \$9,200 per year, not \$207K.	Not Covered	EBRx recommends exclusion of all oxybate products (Xyrem, Lumryz, and Xywav) due to costs, availability of a lower cost alternative (Wakix, pitolisant) for narcolepsy with cataplexy. Pitolisant also lacks the potential for being used illicitly as a date-rape drug and is not a controlled substance. At max dose, here are the comparative annual AWP costs: Sodium oxybate (Lumryz): \$254,916 Sodium oxybate (Xyrem): \$276,794 Mixed salts oxybate (Xywav): \$254,916 Pitolisant (Wakix): \$106,306. The annualized savings (before discounts) for the 6 current Wakix utilizers represents a (\$276,794-106,306)*6= \$1,022,928 annualized savings by keeping oxybate excluded in all forms and using pitolisant as the treatment of narcolepsy with cataplexy.	0; also 0 for Xyrem and Xywav	\$11,666 to \$17,666 per month	
ABRYSVO INJ AREXVY INJ	September 2023 September 2023	Respiratory syncytial virus (RSV) Respiratory syncytial virus (RSV)	Not Covered Not Covered	Standard vaccine list - \$0* Standard vaccine list - \$0*	Align with Navitus rationale: *Recommend zero copay in ages 60+ based on CDC recommendations. Align with Navitus rationale: *Recommend zero copay in ages 60+ for men and women, under 60 years of age for women only (to prevent severe RSV in infants for pregnant women) based on CDC recommendations.	0; not currently covered 0; not currently covered	WAC: \$295/injection WAC: \$280/injection	

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Q3 P&T								
JAYPIRCA TAB	September 2023	Relapsed or refractory (R/R) mantle cell lymphoma (MCL) after ≥ 2 lines of systemic therapy, including a BTK inhibitor	NC	Not Covered	Jaypirca was studied in the single arm trial with no evidence of improvement overall survival or quality of life to date. EBRx recommends excluding pirtobrutinib until data demonstrates an improvement in overall survival and/or quality of life. Alternative: Tecartus	0; not currently covered	\$20,300/month	
ORSERDU TAB	September 2023	Postmenopausal women or adult men with ER+, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor 1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following ≥ 1 line of endocrine therapy.	NC	Not Covered	Orserdu improved progression free survival compared to standard chemotherapy with no apprent improvement in toxicity rates. There was a trend in improved overall survival but statistical significance was not reached at the interim analysis. EBRx recommends excluding elacestrant until data demonstrates an improvement in overall survival and/or quality of life. Alternatives: fulvestrant, anastrozole, letrozole	0; not currently covered	\$20,260/month	
FILSPARI TAB	September 2023	IgA nephropathy: Reduction of proteinuria in adults with IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g	NC	Not Covered	EBRx recommends exclusion unless/until the drug establishes whether the drug slows kidney function decline in patients with IgAN. To date the drug was shown to reduce proteinuria in adults with IgAN through FDA's accelerated approval pathway based on reduction in proteinuria and continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory clinical trial. Given the uncertainty with any clinical benefit, the high cost of the drug, and the REMS program for hepatotoxicity and birth defects, EBRx recommends exclusion until/unless CLINICAL benefit is established.	0; not currently covered	\$10,360/month	
SKYCLARYS CAP	September 2023	Friedreich Ataxia	NC	Not Covered	EBRx recommends exclusion of this drug. In the pivotal trial, a surrogate endpoint (mean difference from placebo of "mFARS" @48 weeks) was the primary endpoint. The minimal clinical important difference for a patient to feel an improvement on the mFARs scale is 5.51 points. Though the difference found was statistically significant (likely not due to chance), they failed to reach the MCID. They found a change from placebo of 2.40 points, not 5.51 points. Due to Skyclarys being a low value drug (possibly even a NO value drug), EBRx recommends exclusion.	0; not currently covered	\$30,525/month	
DAYBUE SOLN	September 2023	Rett Syndrome	NC	Not Covered	EBRx recommends exclusion due to the drug lacks any meaningful clinical endpoint. Although it achieved a statistically significant finding the the primary endpoint (Rett Syndrome Behavior Questionnaire (RSBQ), the mean 12 week scores showed a mean difference from placebo of -3.2 points on a 90 point scale. The mean difference from placebo for the CGI-I questionnaire was -0.3 (95%CI -0.5, -0.1) points. The MCID has not been established in RSBQ or CGI-I for Rett Syndrome. Therefore it is unknown whether or not the drug provides any improvement in health for a Rett's patient. The lack of any known clinical effect that a patient would feel, together with the high cost (annual AWP cost of \$445,587-\$1,184,976) are why EBRx recommends exclusion. EBRx plans to re-evaluate, looking for more peer-reviewed literature, in May 2024.	0; not currently covered	\$42,000/month	

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JOENJA TAB	September 2023	Activated phosphoinositide 3-kinase delta syndrome (APDS) - condition that results in general immune dysregulation	NC	Not Covered	The EBRx P&T Committee voted to exclude the drug based on the absence of evidence showing improvement in clinical endpoints. The clinical trial of 31 PI3Kδ patients measured as the primary endpoint differences from baseline for sizes of index lymph node and the percentage of naïve B cells out of total B cells. The secondary and exploratory endpoints showed that of the 8 leniolisib patients who reported the greatest improvement, the presence or absence of infections appeared to remain unchanged, but main symptoms of lymphadenopathy or gastrointestinal manifestations improved in 4 of them. Additionally, patients in the leniolisib group on average reported increased well-being on the patient global assessment, but the results were not statistically significant at day 85, with adjusted mean change of 9.25 (95%CI - 5.65, 24.14). For these reasons, the Committee voted to exclude from coverage due to the drug lacking clinical endpoint data showing improvement (mainly reduction in infections) with the drug.	0; not currently covered	\$43,470/month	
Misc Cleanup								
TRIKAFTA GRANULE PAK	September 2023	Cystic Fibrosis	NC	Tier 4, PA, QL = 2 packs/day	Align with Navitus rationale: Trikafta tablets already on formulary. Recommending addition of therapy packets for individuals who are unable to swallow tablets. Tablets cannot be split or crushed; the granule packets allow for ease of administration for members who cannot swallow tablets.	0; Currently 11 on tablets	\$24,685/month (\$24,434/month for tablets)	
HUMIRA INJ	September 2023	Various Inflammatory/Autoimmune Conditions	Tier 2, PA, QL	Tier 4, PA, QL	Align with Navitus rationale: these products were formerly on Tier 2 prior to 7/1 and the same setup was followed during the transition process to avoid disruption. Due to Navitus' rebate contracts, placing these products on Tier 2 results in a loss of rebates, since there are related medications on Tier 4 (all products must be at parity to be eligible for rebates). Placing all of these specialty products on Tier 4 will make them elibigible for rebates. This will ultimately save the plan money and will not have an impact on member pay, since these drugs all go through the Access Guidance programs and are subject to Access Guidance copays, regardless of tier placement.	274	\$7100/month	
ENBREL INJ	September 2023	Various Inflammatory/ Autoimmune Conditions	Tier 2, PA, QL	Tier 4, PA, QL	See Humira entry.	106	\$6904/month	
OLUMIANT TAB	September 2023	Various Inflammatory/ Autoimmune Conditions	Tier 2, PA, QL	Tier 4, PA, QL	See Humira entry.	10	\$2623/month	
RINVOQ TAB	September 2023	Various Inflammatory/ Autoimmune Conditions	Tier 2, PA, QL	Tier 4, PA, QL	See Humira entry.	68	\$6290/month	
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See Humira entry.

136

\$7128/month

Various Inflammatory/

Autoimmune Conditions

Tier 2, PA, QL

Tier 4, PA, QL

September 2023

TALTZ INJ