

1 Quarter 2023 Drug Formulary and Clinical Updates

Date of Notice: 03/01/2023

Formulary Updates

Drug Name, Strength(s), & Dosage Form(s)	Description of Change	Formulary Status	Alternative Drug(s) (if applicable)	Effective Date
Xywav 0.5 gram/mL oral solution	Formulary Update; QL Deletion	Non-Preferred Brand		04.01.2023
Onexton 1.2 % (1 % base)-3.75 % topical gel with pump	Formulary Update	Non-Preferred Brand		04.01.2023
Onexton 1.2 % (1 % base)-3.75 % topical gel	Formulary Addition	Non-Preferred Brand		04.01.2023
Xultophy 100/3.6 100 unit-3.6 mg/mL (3 mL) subcutaneous insulin pen	Formulary Update	Non-Preferred Brand		04.01.2023
Dyanavel XR 2.5 mg/mL oral 24 hr ER suspension, Dyanavel XR 5 mg tablet, ER, Dyanavel XR 10 mg tablet, ER, Dyanavel XR 15 mg tablet, ER, Dyanavel XR 20 mg tablet, ER,	Formulary Update	Non-Preferred Brand		04.01.2023
Mounjaro 12.5 mg/0.5 mL subcutaneous pen injector, Mounjaro 15 mg/0.5 mL subcutaneous pen injector, Mounjaro 7.5 mg/0.5 mL subcutaneous pen injector, Mounjaro 10 mg/0.5 mL subcutaneous pen injector, Mounjaro 5 mg/0.5 mL subcutaneous pen injector, Mounjaro 2.5 mg/0.5 mL subcutaneous pen injector	Formulary Update; PA Deletion	Preferred Brand		04.01.2023
Imjudo 20 mg/mL IV solution (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Preferred Brand		04.01.2023
Pedmark 12.5 gram/100 mL (125 mg/mL) IV solution (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Preferred Brand		04.01.2023
Elahere 5 mg/mL IV solution (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Non-Preferred Brand		04.01.2023
Furoscix 80 mg/10 mL subcutaneous wearable injector kit (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		04.01.2023

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Lytgobi 4 mg tablet (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		04.01.2023
Relyvrio 3 gram-1 gram oral powder packet (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		04.01.2023
Rolvedon 13.2 mg/0.6 mL subcutaneous syringe (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Non-Preferred Brand		04.01.2023
Sotyktu 6 mg tablet (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		04.01.2023
Stimufend 6 mg/0.6 mL subcutaneous syringe (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Non-Preferred Brand		04.01.2023
Tzield 1 mg/mL IV solution (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Non-Preferred Brand		04.01.2023
Wakix 4.45 mg tablet, Wakix 17.8 mg tablet	Formulary Addition; PA Addition;	Preferred Brand		04.01.2023
Epiduo Forte 0.3 %-2.5 % topical gel with pump	PA Deletion; QL Deletion	Non-Preferred Brand		04.01.2023
Twynéo 0.1 %-3 % topical cream	PA Deletion	Non-Preferred Brand		04.01.2023
Xyrem 500 mg/mL oral solution	QL Deletion	Preferred Brand		04.01.2023
amphetamine sulfate 10 mg tablet, amphetamine sulfate 5 mg tablet	QL Update	Generic		04.01.2023
Evekeo 10 mg tablet, Evekeo 5 mg tablet, Evekeo ODT 10 mg disintegrating tablet, Evekeo ODT 15 mg disintegrating tablet, Evekeo ODT 20 mg disintegrating tablet, Evekeo ODT 5 mg disintegrating tablet	QL addition	Non-Preferred Brand		04.01.2023
Vegzelma 25 mg/mL IV solution (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		04.01.2023

New Prior Authorization Policies

- RxA.778.Imjudo
- RxA.779.Lytgobi
- RxA.800.Pedmark
- RxA.801.Relyvrio
- RxA.802.Tzield
- RxA.803.Wakix
- RxA.804.Elahere

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- RxA.805.Sotyktu

Updated Prior Authorization Policies

Policy Name	Policy Changes	Effective Date
RxA.018.Aubagio	1. Initial Approval Criteria I.A.6 and Continued Therapy Criteria II.A.3: Updated to add no signs of active infections based on reviewer's feedback.	04.01.2023
RxA.023.Balversa	1. Appendix B, Drug Name: Updated to include therapeutic alternatives <ol style="list-style-type: none"> Tecentriq® Keytruda® Gemcitabine 	04.01.2023
RxA.025.Beleodaq	1. Continued Therapy Approval, II.A.3: Updated dosing criteria from Dose does not exceed FDA prescribing guidelines or dosing is supported by evidence-based guidelines or peer-reviewed literature for the relevant off-label use. *Prescribed regimen must be FDA-approved or recommended by NCCN to Request meets one of the following (a or b):* <ol style="list-style-type: none"> Dose does not exceed 1,000 mg/m² per day on days 1-5 of a 21-day cycle; Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN 	04.01.2023
RxA.028.Step_Therapy_Exception	1. Initial Approval Criteria I.2: Updated from trial and failure of at least two (2) formulary agents to trial and failure of up to two (2) formulary agents.	04.01.2023
RxA.031.Bosulif	1. Initial Approval Criteria, I.A.4 and I.B.3: Updated to include new criteria pertaining to indication Chronic Myelogenous Leukemia, Member does not have the following mutations: T315I, V299L, G250E, or F317L. 2. Appendix B, Drug Name: Updated to include therapeutic alternatives imatinib (Gleevec®).	04.01.2023
RxA.033.Brovana	1. Initial Approval Criteria I.A.5: Updated to include the use of generic arformoterol. 2. Appendix B: Updated to include therapeutic alternatives <ol style="list-style-type: none"> budesonide/formoterol (Symbicort®) fluticasone/salmeterol (Advair Diskus®, Wixela Inhub®) Incruse Ellipta® Tudorza® Pressair® Duaklir® Pressair® Serevent® Striverdi® Respimat® 	04.01.2023

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RxA.038.Binosto_Fosamax .Plus.D	<ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.3: Updated from Medical justification supports inability to use preferred alendronate tablets at maximally indicated doses (e.g., contraindications to the excipients of all Brand and generic products) to Trial and failure of 12 months of alendronate, unless contraindicated or clinically significant adverse effects are experienced; 2. Background: Updated to include Limitation(s) of use for Fosamax® Plus D: Fosamax® Plus D alone should not be used to treat vitamin D deficiency. 	04.01.2023
RxA.041.Bryhali_Lexette_Ultravate	No Updates	04.01.2023
RxA.049.Brineura	No Updates	04.01.2023
RxA.051.Cablivi	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: Updated indication from Diagnosis of aTTP confirmed with a plasmic score of 6 to 7 to Diagnosis of aTTP confirmed with ADAMTS13 activity < 10% of normal or a plasmic score of 6 to 7. 2. Continued Therapy Approval Criteria, II.A.2.ii: Updated to include new response of therapy criteria Member continues to have signs of persistent underlying disease (e.g., suppressed ADAMTS13 activity levels remain present). 3. Appendix B, Therapeutic Alternatives: Remove methylprednisolone (Solu-Medrol®). 4. Appendix D, Warnings and Precautions: Updated to include new warning and precaution, "Avoid concomitant use of Cablivi® with antiplatelet agents or anticoagulants. Interrupt use of Cablivi® if clinically significant bleeding occurs. If needed, von Willebrand factor concentrate may be administered to rapidly correct hemostasis. If Cablivi® is restarted, monitor closely for signs of bleeding." 	04.01.2023
RxA.052.Cabometyx_Cometriq	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: "Request is for one of the following (a or b): <ol style="list-style-type: none"> a. Cabometyx® for advanced renal cell carcinoma; b. Cabometyx®, in combination with nivolumab for patients with advanced renal cell carcinoma, as a first-line treatment" was replaced with Request is for Cabometyx®. 2. Initial Approval Criteria, I.A.5.a, I.A.5.b: Updated dosing criteria from <ol style="list-style-type: none"> a. Dose does not exceed 80 mg per day; b. Cabometyx®, in combination with nivolumab 40 mg for Cabometyx® and 480 mg nivolumab every 4 weeks to <ol style="list-style-type: none"> a. Dose does not exceed 80 mg per day (monotherapy); 	04.01.2023

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	<ul style="list-style-type: none"> b. Dose does not exceed 40 mg per day (combination with Opdivo). 3. Initial Approval Criteria, I.A.5.c: Updated to include new dosing criteria Dose does not exceed 80 mg per day and documentation that member is concurrently taking a strong CYP3A4 inducer. 4. Initial Approval Criteria, I.B.3.b: Updated trial and failure criteria from Who are radioactive iodine-refractory or ineligible to Disease or patient is refractory to radioactive iodine treatment or ineligible. 5. Initial Approval Criteria, I.C.2: Updated prescriber criteria from Prescribed by or in consultation with an oncologist to Prescribed by or in consultation with an oncologist, hepatologist or gastroenterologist. 6. Initial Approval Criteria, I.C.4: updated from “Failure of Nexavar® unless contraindicated or clinically significant adverse effects are experienced” to Request meets one of the following (a, b, c, d or e): <ul style="list-style-type: none"> a. Trial and failure of Nexavar® unless contraindicated or clinically significant adverse effects are experienced; b. Patient has metastatic disease; c. Patient has extensive liver tumor burden; d. Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only); e. Disease is unresectable. 7. Initial Approval Criteria, I.C.5: Updated to include new diagnostic criteria Confirmation of Child-Pugh class A status. 8. Initial Approval Criteria, I.C.7.a: Updated dosing criteria from Dose does not exceed 80 mg per day to Dose does not exceed 60 mg per day. 9. Initial Approval Criteria, I.C.7.b: Updated to include new dosing criteria Dose does not exceed 80 mg per day and documentation that member is concurrently taking a strong CYP3A4 inducer. 10. Initial Approval Criteria, I.D.4: Updated to include new prescribing criteria Prescribed as single-agent therapy for recurrent, advanced or metastatic disease. 11. Appendix D, General Information: Updated to include new information regarding Examples of strong CYP3A4 inducers. 12. Appendix E, Prognostic factors was removed from policy. 	
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<p>RxA.055.Cambia_Zipsor_P ennsaid_Solaraze_Zorvole x</p>	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.3, I.B.5 and I.C.4: Updated trial and failure criteria to remove “at up to maximally indicated doses”. 2. Continued Therapy Approval Criteria, II.A.3: Updated dosing criteria from For Solaraze® requests: additional treatment is for a new lesion or to complete initial treatment (up to 90 days) to For Solaraze®: request for additional treatment of a new lesion or to complete initial treatment of the same lesion and member has not received more than a 90-day treatment. 3. Continued Therapy Approval Criteria, II.4.e: Updated to include dosing criteria Solaraze®: 100 gm per 30 days. 4. Appendix B, Drug Name: Updated to include new therapeutic alternative <ol style="list-style-type: none"> a. 5-fluorouracil (Efudex®, Carac®) 0.5% or 5% topical cream b. imiquimod (Aldara®) topical cream 5. Appendix C: Based on reviewers feedback, Boxed warnings updated to add additional information about elderly patients and those with prior history of peptic ulcer disease are at highest risk for gastrointestinal bleeding. 6. Appendix D, General Information: Updated to include new information regarding actinic keratosis. 	<p>04.01.2023</p>
<p>RxA.061.Ceprotrin</p>	<p>No Updates</p>	<p>04.01.2023</p>
<p>RxA.062.Cerdelga</p>	<ol style="list-style-type: none"> 1. Initial Approval Duration I.A: Approval duration for Commercial and Medicaid updated to 6 months. 	<p>04.01.2023</p>
<p>RxA.063.Cerezyme</p>	<ol style="list-style-type: none"> 1. Background: Updated information regarding pediatric age from indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of type 1 Gaucher disease (GD1) that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, or hepatomegaly or splenomegaly to indicated for long-term enzyme replacement therapy for pediatric 2 years of age and adult patients with a confirmed diagnosis of type 1 Gaucher disease (GD1) that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, or hepatomegaly or splenomegaly. 2. Initial Approval Criteria, member’s current weight, I.A.6: Updated to include new documentation of member’s current weight (in kg). 3. Initial Approval Criteria, I.A.7: Updated to include new dosing criteria Dose does not exceed 60 units/kg every two weeks. 4. Continued Therapy Approval Criteria, member’s current weight, II.A.4: Updated to include new documentation of member’s current weight (in kg). 	<p>04.01.2023</p>

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	5. Continued Therapy Approval Criteria, II.A.5: Updated to include new dosing criteria Dose does not exceed 60 units/kg every two weeks.	
RxA.065.Chenodal	No Updates	04.01.2023
RxA.066.Chloramphenicol sodium succinate	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, chloramphenicol sodium succinate: Updated dosing information from Adult/Pediatric*: 4000 mg/day *Up to 6 g/day may be necessary for pneumococcal meningitis to Adult/Pediatric*: 100 mg/kg/day for indication Infection. 2. Continued Therapy Criteria II.A.2: Updated to add request is for continuation of therapy initiated in an acute care hospital from which member was discharged. 	04.01.2023
RxA.067.Cholbam	No Updates	04.01.2023
RxA.068.Cialis	<ol style="list-style-type: none"> 1. Appendix B, Dosing Regimen, terazosin: Updated dosing information from 5 to 10 mg once daily to Initially, 1 mg once daily at bedtime. Doses are increased to 2 mg, 5 mg, then 10 mg once daily for BPH. 	04.01.2023
RxA.069.Cinqair	<ol style="list-style-type: none"> 1. Initial Approval Criteria, updated to include Cinqair® is not prescribed concurrently with Fasenra®, Nucala®, Dupixent®, or Xolair®. 2. Appendix B, Drug Name: Updated to remove discontinued Brand-name therapeutic alternative <ol style="list-style-type: none"> a. Decadron b. Deltasonec 3. Appendix B, Dosing Regimen, prednisone (Deltasone®): Updated dosing information from 40 to 80 mg orally in 1 to 2 divided doses to 7.5 to 60 mg/day orally once daily for indication asthma. 	04.01.2023
RxA.070.Berinerter_ Cinryze_ Haegarda_ Ruconest	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, recombinant C1 esterase inhibitor (Ruconest®): Updated dosing information from Weight ≥ 84 kg: 4,200 units IV (2 vials) may administer a second dose if symptoms persist to Weight ≥ 84 kg: 4,200 units IV may administer a second dose if symptoms persist for indication Treatment of acute HAE attacks. 2. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of HAE confirmed by one of the following to Diagnosis of HAE confirmed by a history of recurrent angioedema and one of the following. 3. Initial Approval Criteria, I.A.1.b.i: Updated diagnostic criteria from History of recurrent angioedema to Presence of a mutation associated with the disease (see Appendix D). 4. Initial Approval Criteria, I.A.1.b.ii: Updated diagnostic criteria from Family history of angioedema to Family history of angioedema and documented failure of high-dose antihistamine therapy (i.e., cetirizine 40 mg/day or 	04.01.2023

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	<p>equivalent) for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema, whichever is longer.</p> <ol style="list-style-type: none"> 5. Initial Approval Criteria, I.A.4.a: Updated dosing criteria from For treatment of acute HAE attacks, meets one of the following to For treatment of acute HAE attacks, request does not exceed 4 doses per month and meets one of the following. 6. Initial Approval Criteria, I.A.4.b: Updated diagnostic criteria from For prophylaxis of HAE attacks, meets all of the following to For long-term prophylaxis of HAE attacks, meets all of the following. 7. Initial Approval Criteria, I.A.4.c: Updated to include new diagnostic criteria For short-term prophylaxis of HAE attacks, both of the following (i and ii): <ol style="list-style-type: none"> i. Member requires major dental work or surgical procedure; ii. Request does not exceed 2 doses per procedure. 8. Initial Therapy Approval Criteria, I.A: Updated to include new approval criteria Short-term prophylaxis: 4 weeks (no more than 2 doses per procedure). 9. Initial Therapy Approval Criteria, I.A: Updated approval duration criteria for Treatment of HAE attacks: from Medicaid: 12 months to Medicaid: 6 months. 10. Initial Therapy Approval Criteria, I.A: Updated approval duration criteria for Prophylaxis: Commercial: 6 months Medicaid: 12 months to Long-term prophylaxis: Commercial: 6 months Medicaid: 6 months. 11. Continued Therapy Approval, II.A.4: Updated to include new dosing criteria For treatment of acute attacks, request does not exceed 4 doses per month. 12. Continued Therapy Approval, II.A.5.a: Updated dosing criteria from Berinert®: 20 IU/kg of body weight per single dose to Berinert®: 20 IU/kg of body weight per single dose, up to 2 doses administered in a 24-hour period. 13. Continued Therapy Approval, II.A.5.d: Updated dosing criteria from Ruconest®: 4,200 U per single dose, up to 2 doses administered in a 24-hour period to Ruconest®: 4,200 U per single dose, up to 2 doses administered in a 24-hour period, up to 2 doses administered in a 24-hour period. 14. Continued Therapy Approval, II.A: Updated approval duration criteria Prophylaxis to Long-term Prophylaxis. 15. Appendix B, Drug Name: Updated to include therapeutic alternatives: <ol style="list-style-type: none"> a. cetirizine; b. icatibant (Firazyr®). 	
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	<p>16. Appendix D, General Information: Updated information available from There are two classifications of HAE: HAE with C1-INH deficiency (further broken down into Type 1 and Type II) and HAE of unknown origin (also known as Type III) to There are two classifications of HAE: HAE with C1-INH deficiency (HAE-C1INH, further broken down into Type 1 and Type II) and HAE with normal C1-INH (also known as HAE-nl-C1INH). HAE-nl-C1INH was previously referred to as type III HAE, but this term is obsolete and should not be used.</p> <p>17. Appendix D, General Information: Updated information available from Type III, on the other hand, presents with normal C4 and C1-INH levels. Some patients have an associated mutation in the FXII gene, while others have no identified genetic indicators. Type III is very rare (number of cases unknown), and there are no laboratory tests to confirm the diagnosis. Instead, the diagnosis is clinical and supported by recurrent episodes of angioedema with a strong family history of angioedema to HAE-nl-C1INH, on the other hand, presents with normal C4 and C1-INH levels. Some patients have an associated mutation , while others have no identified genetic indicators. HAE-nl-C1INH is very rare, and there are no laboratory tests to confirm the diagnosis. Instead, the diagnosis is clinical and supported by recurrent episodes of angioedema with a strong family history of angioedema.</p> <p>18. Appendix D, General Information: Updated information available from HAE attack triggers may include minor trauma (such as dental procedures), oral contraceptives, and ACE inhibitors to HAE attack triggers may include minor trauma (such as dental procedures).</p> <p>19. Appendix D, General Information: "Bowen T, Cicardi M, Farkas H, et al. recommend plasma-derived C1 inhibitors for short- term prophylaxis: 10 to 20 units per kg one dose 1 hour before surgery or less than 6 hours before procedures (must be given before endotracheal intubation/manipulations) with a second dose of equal amount available during surgery" was replaced with Short-term prophylaxis may be indicated before invasive medical, surgical, or dental procedures. Busse et al recommend that a single dose of 20 units/kg of plasma-derived C1 inhibitor can be given 1 to 12 hours before the stressor. On-demand treatment should also be available in the event of delayed swelling in the wake of the procedure.</p>	
RxA.076.Cortrosyn	<p>1. Initial Approval Criteria I.A.2: Updated to add If Cortrosyn® is requested, member must use generic cosyntropin, unless contraindicated or clinically</p>	04.01.2023

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	<p>significant adverse effects are experienced;</p> <p>2. Appendix C: Updated from history of previous adverse reaction to Cortrosyn® to hypersensitivity to Cosyntropin injection or to any of the excipients.</p>	
RxA.077.Dose_optimization	No update	04.01.2023
RxA.080.Crysvita	<p>1. Initial Approval Criteria, I.B.8: Updated dosing criteria from Dose does not exceed 180 mg every two weeks (pediatrics) or 180 mg every four weeks to Dose does not exceed 180 mg every two weeks (pediatrics) or 180 mg every two weeks (adult).</p> <p>2. Continued Therapy Approval Criteria, II.A.3.b: Updated dosing criteria from For TIO: Dose does not exceed 180 mg every two weeks (pediatrics) or 180 mg every four weeks to For TIO: Dose does not exceed 180 mg every two weeks (pediatrics) or 180 mg every two weeks (adult).</p>	04.01.2023
RxA.083.Cyramza	<p>1. Background: Updated indication from Ramucirumab (Cyramza®) is an anti-vascular endothelial growth factor antibody to Ramucirumab (Cyramza®) is human vascular endothelial growth factor receptor 2 (VEGFR2) antagonist indicated.</p> <p>2. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria Disease is unresectable, locally advanced, recurrent, or metastatic.</p> <p>3. Initial Approval Criteria, I.B.1: Updated indication from Diagnosis of metastatic NSCLC to Diagnosis of metastatic, recurrent, or advanced NSCLC.</p> <p>4. Initial Approval Criteria, I.B.6.a: Updated indication from Dose does not exceed 10 mg per kg on day 1 of a 21-day cycle to In combination with docetaxel: Dose does not exceed 10 mg per kg on day 1 of a 21-day cycle.</p> <p>5. Initial Approval Criteria, I.C.1: Updated indication from Diagnosis of metastatic CRC to Diagnosis of advanced or metastatic CRC.</p> <p>6. Initial Approval Criteria, I.C.4: Updated to include new criteria pertaining to indication Colorectal Cancer, Request is for one of the following (a or b):</p> <ol style="list-style-type: none"> Primary treatment for unresectable metachronous metastases; For subsequent therapy; <p>7. Initial Approval Criteria, I.D.1: Updated indication from Diagnosis of HCC to Diagnosis of progressive HCC.</p> <p>8. Continued Therapy Approval Criteria, II.A.3.b: Updated dosing criteria from NSCLC: new dose does not exceed 10 mg per kg on day 1 of a 21-day cycle to NSCLC in combination with docetaxel: new dose does not exceed 10 mg per kg on day 1 of a 21-day cycle.</p>	04.01.2023

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	9. Appendix B, Drug Name: Updated to include generic therapeutic alternative sorafenib and Ta.	
RxA.084.Cystagon_Procysbi	1. Initial Approval Criteria, approval duration: Updated from 12 months to 6 months.	04.01.2023
RxA.085.Cystaran	No update	04.01.2023
RxA.086.Compounded_Medications	<ol style="list-style-type: none"> 1. Initial Approval Criteria: I.A.2.a: Updated to add examples of medical justification supports inability to use commercially available FDA- approved products. 2. Initial Approval Criteria I.A.3: Updated to add Acceptable compendium supports efficacy and safety for the indicated treatment (see Appendix D); 3. Appendix D: Updated to be added examples of acceptable compendia. 	04.01.2023
RxA.087.Cystadane	No update	04.01.2023
RxA.088.Daraprim	<ol style="list-style-type: none"> 1. Background: Updated indication from Daraprim® is a folic acid antagonist. It is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide to Daraprim® is a folic acid antagonist. It is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination. 2. Dosing Information, Footnote: Updated to include new footnote regarding *Off-label uses. 3. Initial Approval Criteria, I.B.4: “CD4 count < 100 cells/mm³” was replaced with Member meets one of the following (a or b): CD4 count < 100 cells/mm³; <ol style="list-style-type: none"> a. Age ≥ 6 years: CD4 count < 100 cells/mm³; b. Age < 6 years: CD4 cell percentage < 15%. 4. Continued Therapy Approval, II.A.2: “Member is HIV-infected with CD4 count ≤ 200 cells/mm³ at any time in the previous 6 months” was replaced with Member is HIV-infected with one of the following (a or b): <ol style="list-style-type: none"> a. Age ≥ 6 years: CD4 count ≤ 200 cells/mm³ at any time in the previous 6 months; b. Age < 6 years: CD4 percentage has risen < 15% from baseline at any time in the previous 6 months. 5. Continued Therapy Approval, II.B.2: “Member is HIV-infected with CD4 count ≤ 200 cells/mm³ at any time in the previous 3 months” was replaced with Member is HIV-infected with one of the following (a or b): <ol style="list-style-type: none"> a. Age ≥ 6 years: CD4 count ≤ 200 cells/mm³ at any time in the previous 3 months; b. Age < 6 years: CD4 percentage has risen < 15% from baseline at any time in the previous 3 months. 	04.01.2023
RxA.089.CNS_Stimulants	1. Dosing Information, Dosing Regimen, mixed salts of a single-entity amphetamine product ER (Mydayis®):	04.01.2023

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	<p>Updated to include renal impairment dosing information for indication ADHD.</p> <ol style="list-style-type: none"> 2. Dosage Forms: Updated to include new dosage form, extended-release tablets for drug amphetamine (Dyanavel XR®). 3. Initial Approval Criteria, I.A.4.a: Updated dosing criteria from Adhansia XR®: 85 mg per day to Adhansia XR™: 85 mg per day (adults); 70 mg/day (pediatric). 4. Continued Therapy Approval Criteria, II.A.3.a: Updated dosing criteria from Adhansia XR®: 85 mg per day to Adhansia XR®: 85 mg per day (adults); 70 mg/day (pediatric). 5. Appendix B, Maximum Dose, Adderall XR®: Updated maximum dose information from Patients 6 years and older: 40 mg/day to 30 mg/day for indication ADHD and included Adults: 20 mg/day. 	
RxA.090.Total_Parenteral_Nutrition_and_Intradialytic_Parenteral_Nutrition	<ol style="list-style-type: none"> 1. Approval Criteria, I.A.2.i: Updated to include new diagnostic criteria Radiation enteritis. 2. Approval Criteria, I.A.2.j: Updated to include new diagnostic criteria Liver failure in children approved for liver transplants, who fail to grow while receiving enteral nutritional support. 3. Approval Criteria, I.A.2.k: Updated to include new diagnostic criteria Liver failure in adults who have hepatic encephalopathy and cannot tolerate a protein source consisting of standard amino acids or enteral nutritional support (TPN used for the administration of a liver-specific amino acid mixture). 4. Approval Criteria, I.A.2.l: Updated to include new diagnostic criteria Acute necrotizing pancreatitis in adults with an inadequate oral intake for longer than a week, where enteral feedings exacerbate abdominal pain, ascites, or fistulous output. 	04.01.2023
RxA.094.Nocturna_Noctiva	<ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.6.c: Updated contraindication/adverse event criteria from New York Heart Association class II to IV congestive heart failure to Heart failure (For Noctiva™: New York Heart Association class II to IV Congestive heart failure). 	04.01.2023
RxA.096.Desoxyn	<ol style="list-style-type: none"> 1. Appendix B, Drug Name: Updated to include therapeutic alternatives: <ol style="list-style-type: none"> a. Adzenys XR-ODT™ b. Adhansia XR™ c. methylphenidate ER (Aptensio XR®) d. Jornay PM® e. Cotempla XR-ODT™ f. dexmethylphenidate ER (Focalin XR®) 	04.01.2023
RxA.097.Blood_glucose_test_strip_quantity_limit - Not_Receiving_Insulin	No update	04.01.2023

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RxA.099.Duexis	<ol style="list-style-type: none"> 1. Appendix B, Dosing Regimen, piroxicam (Feldene®): Updated dosing information from 10- 20 mg orally once daily to 20 mg orally once daily. 2. Approval duration was reviewed and updated. 	04.01.2023
RxA.100.Dysport	<ol style="list-style-type: none"> 1. Dosing Information, Maximum Dose, abobotulinumtoxinA (Dysport®): Updated to maximum dosing information from Adults: 1,000 units/12 weeks to Adults: 1,500 units/12 weeks for indication Upper limb spasticity. 2. Dosing Information, Dosing Regimen, abobotulinumtoxinA (Dysport®): Updated to include dosing information for Re-treatment Re-treatment, based on return of clinical symptoms, should not occur in intervals of less than 3 months for indication Lower limb spasticity. 3. Initial Approval Criteria, I.A.6, I.C.5 and I.D.6: Updated to include new criteria pertaining to indication CD, Upper and Lower Limb Spasticity in Adults and Pediatric Upper and Lower Limb Spasticity Member meets both of the following (a and b): <ol style="list-style-type: none"> a. Dysport® is not prescribed concurrently with other botulinum toxin products; b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks; 4. Initial Approval Criteria, I.B: Updated to replace all existing criteria with Non authorized indication due to its cosmetic nature for Glabellar Lines. 5. Continued Therapy Approval Criteria, II.A.5: Updated to include new criteria pertaining to indication CD, Upper and Lower Limb Spasticity in Adults and Pediatric Upper and Lower Limb Spasticity Member meets both of the following (a and b): <ol style="list-style-type: none"> a. Dysport® is not prescribed concurrently with other botulinum toxin products; b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks; 6. Continued Therapy Approval Criteria, II.A.6.a: Updated dosing criteria from Adults: CD, upper limb spasticity: 1,000 units, lower limb spasticity: 1,500 units, Glabellar Lines: 50 units to Adults: CD: 1,000 units, Upper and lower limb spasticity: 1,500 units. 7. Continued Therapy Approval Criteria, II.B: Updated to replace all existing criteria with Non authorized indication due to its cosmetic nature for Glabellar Lines. 8. Appendix B, Drug Name: Updated to include new therapeutic alternative carbidopa/levodopa (Sinemet®, Duopa®, Rytary®) and trihexyphenidyl. 	04.01.2023

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RxA.102.Daurismo	1. Initial Approval Criteria I.A.3.c: Updated to add Member responded to then relapsed after Daurismo induction therapy \geq 12 months ago.	04.01.2023
RxA.109.Edluar_Intermezzo_Zolpimist	1. Initial Approval Criteria and Continued Therapy Criteria: Approval duration, Commercial updated to 12 months from 6 months.	04.01.2023
RxA.111.Egrifta_SV	1. Appendix D: Updated to remove previous information about belly fat and updated to add On June 15, 2020, Theratechnologies discontinued Egrifta and permanently replaced it with Egrifta SV, a smaller volume injection able to be stored at room temperature.	04.01.2023
RxA.112.Elaprase	1. Initial Approval Criteria, member's current weight, I.A.3: Updated to include new documentation of member's current weight (in kg). 2. Continued Therapy Approval Criteria, member's current weight, II.A.3: Updated to include new documentation of member's current weight (in kg).	04.01.2023
RxA.113.Elelyso	1. Initial Approval Criteria, member's current weight, I.A.6: Updated to include new documentation of member's current weight (in kg). 2. Initial Approval Criteria, I.A.7: Updated to include new dosing criteria Dose does not exceed 60 units/kg every two weeks. 3. Continued Therapy Approval Criteria, member's current weight, II.A.4: Updated to include new documentation of member's current weight (in kg). 4. Continued Therapy Approval, II.A.5: Updated to include new dosing criteria If request is for a dose increase, new dose does not exceed 60 units/kg every 2 weeks.	04.01.2023
RxA.116.Enstilar	No update	04.01.2023
RxA.117.Fabrazyme	1. Initial Approval Criteria, I.A.3: Updated to include new prescriber criteria Prescribed by or in consultation with a clinical geneticist, cardiologist, nephrologist, neurologist, lysosomal disease specialist, or Fabry disease specialist. 2. Initial Approval Criteria, I.A.4: Updated to include new prescribing criteria Fabrazyme is not prescribed concurrently with Galafold®.	04.01.2023
RxA.118.Faslodex	1. Initial Approval Criteria, I.D.3: Updated to include new diagnostic criteria Disease is classified in one of the following ways (a, b, or c): a. Low-grade endometrial stromal sarcoma; b. Adenosarcoma without sarcomatous overgrowth; c. HR-positive (i.e., ER/PR-positive) uterine leiomyosarcoma.	04.01.2023
RxA.120.Firdapse_Ruzurgi	1. Background: Updated indication from Firdapse® is approved for use in adults for treatment of LEMS to Firdapse® is approved for use in adults and pediatric	04.01.2023

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	<p>patients 6 years of age and older for treatment for LEMS.</p> <ol style="list-style-type: none"> 2. Dosing Information, Dosing Regimen, amifampridine (Firdapse®): Updated to include dosing information for pediatric patients (Age 6 to 17 years- Weight Less than 45 kg and 45 kg or greater) for indication LEMS. 3. Dosing Information, Maximum Dose, amifampridine (Firdapse®): Updated to include maximum dosing information for pediatric patients (Age 6 to 17 years- Weight Less than 45 kg and 45 kg or greater) for indication LEMS. 4. Dosing Information, Dosing Regimen, amifampridine (Firdapse®): Updated to include hepatic and renal impairment dosing pediatric patients (Age 6 to 17 years- Weight Less than 45 kg and 45 kg or greater) for indication LEMS. 5. Initial Approval Criteria I.A.4: Updated to remove member has proximal muscle weakness. 6. Initial Approval Criteria I.A.5: Updated to remove member does not have a history of seizures. 7. Initial Approval Criteria I.A.6: Updated to remove member is not receiving amifampridine in combination with similar potassium blockers (e.g., dalfampridine). 8. Initial Approval Criteria, I.A.3.a: Updated age criteria from ≥ 18 years of age for Firdapse® to Age ≥ 6 years for Firdapse®. 9. Initial Approval Criteria, I.A.8.a.ii and iii: Updated to include new dosing criteria: <ol style="list-style-type: none"> a. Pediatric (6 to 17 years) (Less than 45 kg): 40 mg/day. b. Pediatric (6 to 17 years) (45 kg or greater): 80 mg/day. 10. Continued Therapy Approval, II.A.5.a.ii and iii: Updated to include new dosing criteria: <ol style="list-style-type: none"> a. Pediatric (6 to 17 years) (Less than 45 kg): 40 mg/day. b. Pediatric (6 to 17 years) (45 kg or greater): 80 mg/day. 11. Appendix D: Updated to add information about Ruzurgi not available commercially. 	
RxA.121.Folotyn	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4.a: Updated to include new prescribing criteria Prescribed as initial palliative intent therapy. 2. Initial Approval Criteria, I.A.5: Updated to include new prescribing criteria Prescribed as a single-agent therapy. 	04.01.2023
RxA.122.Fortamet_Glume tza	<ol style="list-style-type: none"> 1. Background: Updated to remove limitation(s) of use, "These products should not be used in patients with type 1 DM or for the treatment of diabetic ketoacidosis, as they would not be effective in these settings." 	04.01.2023

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RxA.125.Fuzeon	No update	04.01.2023
RxA.127.Farydak	<ol style="list-style-type: none"> Appendix B, Dosing Regimen, liposomal doxorubicin (Doxil®): Updated dosing information from 30 mg/m2 IVly over 1 hour on day 4 repeated every 4 weeks; used in combination with bortezomib to 30 mg/m2 IVly over 1 hour on day 4 repeated every 3 weeks; used in combination with bortezomib for indication MM. Appendix B, Drug Name: Updated to include generic therapeutic alternative lenalidomide. Appendix D, General Information: Updated to include new information regarding withdrawal of NDA for Farydak. 	04.01.2023
RxA.129.Firmagon	<ol style="list-style-type: none"> Appendix B, Drug Name: Updated to add therapeutic alternatives <ol style="list-style-type: none"> leuprolide (Lupron Depot®) Zoladex® triptorelin (Trelstar®) leuprolide acetate (Eligard®) 	04.01.2023
RxA.130.Auryxia_Renagel_Velphoro	<ol style="list-style-type: none"> Dosing Information, Dosing Regimen, sevelamer hydrochloride (Renagel®): Updated dosing information from Starting dose based on serum phosphorus level to Starting dose for adult dialysis patients based on serum phosphorus level. If serum phosphorus is for indication Hyperphosphatemia. Initial Approval Criteria I.A..4.a and I.B.3: Updated to remove maximally indicated doses. Appendix B, Dosing Regimen, sevelamer carbonate (Renvela®): Updated dosing information from ≥ 0.75 to < 1.2: 0.8 mg orally three times w/ meals to ≥ 0.75 to < 1.2: 0.8 gm orally three times w/ meals for indication Hyperphosphatemia for Starting dose for pediatric patients (6 years and older) based on body surface area (BSA). 	04.01.2023
RxA.131.Neulasta_Fulphila_Udenyca_Ziextenzo_Stimufend_Rolvedon	<ol style="list-style-type: none"> Clinical Policy Title: Updated to include pegfilgrastim-fpgk and eflapegrastim-xnst. Clinical Policy Title, Drug(s) Applied: Updated to include new Brand Stimufend® and Rolvedon™. Background: Updated to include Stimufend® and Rolvedon™ under indication Myelosuppressive chemotherapy. Background: Updated to include Udenyca® under indication Acutely exposed to myelosuppressive doses of radiation Dosing Information, Drug Name: Updated to include new drug pegfilgrastim-fpgk (Stimufend®) and eflapegrastim-xnst (Rolvedon™) for indication Myelosuppressive chemotherapy. Dosing Information, Drug Name: Updated to include pegfilgrastim-cbqv (Udenyca®) for indication Acutely 	04.01.2023

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	<p>exposed to myelosuppressive doses of radiation.</p> <ol style="list-style-type: none"> 7. Dosage Forms: Updated to include new Brand dosage form <ol style="list-style-type: none"> a. pegfilgrastim-fpgk (Stimufend®): 6 mg/0.6 mL solution in a single-dose pre-filled syringe for manual use only. b. eflapegrastim-xnst (Rolvedon™): 13.2 mg/0.6 mL solution in a single-dose prefilled syringe. 8. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of non-myeloid malignancy to Diagnosis of non-myeloid malignancy (i.e., solid tumor and lymphoid malignancies). 9. Initial Approval Criteria, I.A.5: Updated to add Confirmation that there is at least 12 days between pegfilgrastim/eflapegrastim-xnst dose and the next cycle of chemotherapy. 10. Initial Approval Criteria, I.A.7: Updated dosing criteria from Dose does not exceed 6 mg (1 syringe) per chemotherapy cycle to Dose does not exceed one of the following (a or b): <ol style="list-style-type: none"> a. For pegfilgrastim: 6 mg (1 syringe) per chemotherapy cycle; b. For eflapegrastim: 13.2 mg (1 syringe) per chemotherapy cycle 11. Initial Approval Criteria, I.B and I.C: Updated to include new request criteria Request is not for Rolvedon™. 12. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Wilms Tumor (off-label). 13. Initial Approval Criteria, I.C: Updated to remove approval criteria for Compendial Indications (off-label). 14. Continued Therapy Approval, II.A.3.a: Updated dosing criteria from Chemotherapy-induced neutropenia: 6 mg administered once per chemotherapy cycle to Chemotherapy-induced neutropenia (i or ii): <ol style="list-style-type: none"> i. For pegfilgrastim: 6 mg administered once per chemotherapy cycle; ii. For eflapegrastim: 13.2 mg (1 syringe) per chemotherapy cycle; 15. Continued Therapy Approval, II.A.3.c: Updated dosing criteria to remove Bone marrow transplantation: 6 mg per dose, or dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (provider must submit supporting evidence). 16. Continued Therapy Approval, II.A.3.d: Updated to include new dosing criteria Wilms tumor: 6 mg (1 syringe) administered once per chemotherapy cycle for Wilms tumor. 17. Appendix B, Drug Name: Updated to remove therapeutic alternatives: 	
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	<ul style="list-style-type: none"> a. Neupogen®; b. Zarxio®; c. Granix®; d. Nivestym®; e. Leukine®. <p>18. Appendix D, General Information: Updated to include new information regarding Chemotherapy regimens used in the treatment of Wilms Tumor for which filgrastim supportive care may be considered.</p> <p>19. Appendix D, General Information: Updated to remove information “The NCCN Compendium recommends pegfilgrastim for supportive care post autologous hematopoietic cell transplant (category 2A).”</p>	
RxA.136.Firazyr	<ol style="list-style-type: none"> 1. Dosage Forms: Updated dosage form from 10 mg per mL to 10 mg per mL (30mg/3ml). 2. Initial Approval Criteria I.A.5 and Continued Therapy Criteria II.A.3: Updated to add request does not exceed 6 doses per month. 3. Initial Approval Criteria and Continued Therapy Criteria: Approval Duration updated to add Up to 6 doses per month. 4. Initial Approval Criteria: Approval duration for Medicaid and Commercial plan updated from 12 months to 6 months. 5. Appendix B, Drug Name: Updated to include new therapeutic alternative cetirizine. 	04.01.2023
RxA.137.Formulary Exceptions	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.3.b: Updated to include new trial and failure criteria Documented contraindication(s) or clinically significant adverse effects to all formulary agents within the same therapeutic class or formulary drugs that are recognized as standards of care for the treatment of member’s diagnosis. 2. Initial Approval Criteria, I.A.4: Updated to include new combination therapy criteria For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products); *Use of a copay card or discount card does not constitute medical necessity 3. Initial Approval Criteria, 1.D.2: Updated trial and failure criteria from Trial and failure of an adequate trial of or clinically significant adverse effects to two generics* of the requested Brand name drug, each from a different manufacturer, unless member has contraindications to the excipients in all generics to Trial and failure of an adequate trial of or clinically significant adverse effects to two generics* of the requested Brand name drug, 	04.01.2023

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	<p>each from a different manufacturer, or the preferred biosimilar(s) unless member has contraindications to the excipients in all generics.</p> <ol style="list-style-type: none"> 4. Initial Approval Criteria, I.E: Updated to remove approval criteria for Exceptions for combination products and alternative dosage forms or strengths of Existing Drugs. 5. Initial Approval Criteria, 1.E.1: Updated to include new requesting criteria Request is for a formulary drug without custom coverage criteria; *All requests for non-formulary drugs, should be reviewed against Section I.A Exceptions for Non-Formulary or Tier 3 Drugs above 6. Initial Approval Criteria, I.E.2.a: Updated to remove prior diagnostic criteria "Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);". 7. Initial Approval Criteria, I.E.2.b: Updated to include new diagnostic criteria Diagnosis of one of the following (a or b): <ol style="list-style-type: none"> a. Prescribed indication is FDA-approved; b. A condition supported by the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, or 2A. 8. Initial Approval Criteria, I.E.4: Updated to include new combination therapy criteria For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products); *Use of a copay card or discount card does not constitute medical necessity. 9. Initial Therapy Approval Criteria, I.E: Updated approval duration criteria for Exceptions for Drugs Requiring Prior Authorization without Custom Coverage Criteria from: Commercial: 6 months Medicaid: 6 months to Commercial: 12 months Medicaid: 12 months. 	
RxA.138.Forteo	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: "Diagnosis of osteoporosis" was replaced with Diagnosis of PMO, GIO, or male osteoporosis and one of the following (a or b): <ol style="list-style-type: none"> a. Member is at very high risk for fracture as evidenced by one of the following (i, ii, or iii): <ol style="list-style-type: none"> i. Recent osteoporotic fracture (within the past 12 months); 	04.01.2023

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	<ul style="list-style-type: none"> ii. Bone mineral density (BMD) T-score at hip or spine ≤ -3.0; iii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus); b. Member has completed a 3-year trial of bisphosphonate therapy (see Appendix B; alendronate is preferred) at up to maximally indicated doses, unless one of the following (i-v): <ul style="list-style-type: none"> i. All bisphosphonates are contraindicated; ii. Clinically significant adverse effects are experienced to both IV and oral formulations (see Appendix D); iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy; iv. Member has experienced a lack of BMD increase after ≥ 12 months of bisphosphonate therapy; v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy; <p>*Prior authorization may be required for bisphosphonates.</p> <ol style="list-style-type: none"> 2. Initial Approval Criteria, I.A.3.b: Updated to remove prior trial and failure criteria "Failure of a 12-month trial of a bisphosphonate (alendronate is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced". 3. Appendix B, Drug Name: Updated to include therapeutic alternatives: <ul style="list-style-type: none"> a. Tymlos® b. Prolia® 4. Appendix D, General Information: Updated to include new information regarding Clinical practice guidelines include patient profiles representing examples of high and very high fracture risk. 5. Appendix D: Updated to add information about FRAX tool and its clinical risk factors. 	
RxA.140.Fusilev	<ol style="list-style-type: none"> 1. Appendix D, General Information: Updated NCCN guidelines recommend the combination use of levoleucovorin with methotrexate to include indication Pediatric Acute Lymphoblastic Leukemia. 	04.01.2023
RxA.141.Gablofen_Lioresa I_Ozobax	No update	04.01.2023
RxA.142.Gamifant	<ol style="list-style-type: none"> 1. Dosage Forms: Updated dosage form from Single-dose vial: 10 mg/2 mL, 50 mg/10 mL, 100 mg/20 mL to Single-dose vial (5 mg/mL) solution: 10 mg/2 mL, 50 mg/10 mL, 100 mg/20 mL. 	04.01.2023

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	<ol style="list-style-type: none"> 2. Initial Approval Criteria, I.A.2, I.A.2.a, I.A.2.b & I.A.2.c.viii: Updated to include new criteria pertaining to indication Primary Hemophagocytic Lymphohistiocytosis, Diagnosis confirmation. 3. Initial Approval Criteria, I.A.2.c.iii: Updated diagnostic criteria from Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin < 9, platelets to Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin < 9, platelets < 100 x 10⁹ /L, neutrophils < 1 x 10⁹ /L). 4. Initial Approval Criteria I.A.6: Updated to remove member does not have any active infections caused by to specific pathogens favoured by IFNγ neutralization, including mycobacteria, Herpes Zoster virus, and Histoplasma Capsulatum; Documentation of latent tuberculosis (TB) test result (purified protein derivative test or IFNγ release assay) showing negative result or supporting documentation showing member is taking prophylactic TB treatment (e.g. isoniazid) if member is at risk for TB, or known to have a positive test result. 5. Initial Approval Criteria I.A.7: Updated to remove members should have documented concurrent dexamethasone therapy or plan to initiate it. 6. Appendix B: Updated to remove therapeutic alternatives cyclosporine A and methotrexate. 	
<p>RxA.143.Immune_Globulin</p>	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.D.3: Updated to include new diagnostic criteria “Member meets one of the following (a - b): <ol style="list-style-type: none"> a. Diagnosis is AIDP/GBS and member meets one of the following (i-vii): <ol style="list-style-type: none"> i. Inability to stand or walk at least 30 feet without assistance; ii. ICU admission required for aspiration or mechanical ventilation; iii. Miller-Fisher syndrome; iv. Inability to raise head against gravity; v. Severe bulbar palsy (e.g., impaired gag reflex, dysarthria and/or dysphagia); vi. Bilateral facial weakness; vii. Autonomic dysfunction (e.g., unexplained dysrhythmia, blood pressure fluctuations, significant bowel or bladder involvement); b. Diagnosis is CIDP and member meets all of the following (i-v): <ol style="list-style-type: none"> i. Disease is progressive or relapsing for more than 2 months; ii. Member has either of the following (a or b): <ol style="list-style-type: none"> a. Both of the following, characterizing typical CIDP (1 and 2): <ol style="list-style-type: none"> 1. Chronically progressive, stepwise, or 	<p>04.01.2023</p>

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	<p>recurrent symmetric proximal and distal weakness and sensory dysfunction of all extremities;</p> <ol style="list-style-type: none"> 2. Absent or reduced tendon reflexes in all extremities; <p>b. One of the following, characterizing atypical CIDP (1-3):</p> <ol style="list-style-type: none"> 1. Predominantly distal (distal acquired demyelinating symmetric, DADS) or asymmetric [multifocal acquired demyelinating sensory and motor neuropathy (MADSAM), Lewis-Sumner syndrome] or focal (e.g., involvement of the brachial or lumbosacral plexus or of one or more peripheral nerves in one upper or lower limb) disease; 2. Pure motor symptoms; 3. Pure sensory symptoms (including chronic immune sensory polyradiculopathy affecting the central process of the primary sensory neuron); <p>iii. Diagnosis has been confirmed via electrodiagnostic testing.</p> <p>iv. Member does not have any of the following (1-6):</p> <ol style="list-style-type: none"> 1. <i>Borrelia burgdorferi</i> infection (Lyme disease), diphtheria, drug or toxin exposure probably to have caused the neuropathy; 2. Hereditary demyelinating neuropathy; 3. Prominent sphincter disturbance; 4. Diagnosis of multifocal motor neuropathy; 5. IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein; 6. Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and nondiabetic lumbosacral radiculoplexus neuropathy; <p>v. For members who do not have pure motor symptoms, failure of at least one corticosteroid (e.g., prednisone) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced.</p>	
RxA.145.Gilenya	1. Initial Approval Criteria, I.A.5: Updated to include new documentation criteria Documentation of baseline	04.01.2023

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	number of relapses per year and expanded disability status scale (EDSS) score.	
RxA.157.Neupogen_Zarxio_Nivestym_Granix_Releuko	<ol style="list-style-type: none"> 1. Dosing Information, Indication: Updated from Severe neutropenia to Severe neutropenia (In nonmyeloid malignancies following myelosuppressive chemotherapy; Prophylaxis) for Granix®. 2. Initial Approval Criteria, I.A.4, I.B.4, I.C.5, I.D.3, I.E.4, I.F.4 and I.G.4: Updated to include new prescribing criteria The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., pegfilgrastim, Leukine®) within any chemotherapy cycle. 3. Initial Approval Criteria, I.F.3: Updated trial and failure criteria from For Neupogen®, Releuko®, Granix® requests, member has had a failure with Nivestym™ or Zarxio®*, unless contraindicated or clinically significant adverse effects are experienced to For Neupogen®, Releuko®, Granix® requests, member has had a failure with Nivestym™ or Zarxio®*, unless contraindicated or clinically significant adverse effects are experienced; 4. Initial Approval Criteria, I.G.3: Updated trial and failure criteria from Member has had a failure with Zarxio® or Nivestym™, unless contraindicated or clinically significant adverse effects are experienced to For Neupogen® or Releuko® request, member has had a failure with Zarxio® or Nivestym™, unless contraindicated or clinically significant adverse effects are experienced; 5. Continued Therapy Approval, II.A.3 : Updated to include new prescribing criteria The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., pegfilgrastim, Leukine®) within any chemotherapy cycle. 	04.01.2023
RxA.207.Minastrin.24.Fe_Taytulla_Gemmily	<ol style="list-style-type: none"> 1. Appendix D, General Information: Updated to remove information regarding outdated information. 2. Appendix D, General Information: Updated information available from efficacy of Taytulla® and Minastrin 24 Fe® in women with a body mass index (BMI) of more than 35 kg/m² has not been evaluated to efficacy of Taytulla®, Gemmily® and Minastrin 24 Fe® in women with a body mass index (BMI) of more than 35 kg/m² has not been evaluated. 	04.01.2023
RxA.256.Quantity_Limit_Override	No update	04.01.2023
RxA.304.Otrexup_Rasuvo_Xatmep_Reditrex_Jylamvo	<ol style="list-style-type: none"> 1. Background: Updated to include indication for new Brand Jylamvo®: <ul style="list-style-type: none"> • Treatment of adults with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen. 	04.01.2023

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	<ul style="list-style-type: none"> • Treatment of adults with mycosis fungoides. • Treatment of adults with relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen. • Treatment of adults with rheumatoid arthritis. • Treatment of adults with severe psoriasis. <ol style="list-style-type: none"> 2. Dosing Information, Drug Name: Updated to include new drug methotrexate oral solution (Jylamvo®). 3. Dosing Information, Dosing Regimen, methotrexate oral solution (Jylamvo®): Updated to include dosing information for indication ALL, MF, Relapsed or refractory non-Hodgkin lymphoma, RA and PsO. 4. Dosing Information, Maximum Dose, methotrexate oral solution (Jylamvo®): Updated to include maximum dosing information for indication ALL, MF, Relapsed or refractory non-Hodgkin lymphoma, RA and PsO. 5. Dosage Forms, methotrexate oral solution (Jylamvo®) Updated to include new dosage form, 2 mg/mL in a 60 mL. 6. Initial Approval Criteria, I.B.2: Updated request criteria from Request is for Otrexup™, Rasuvo® or Reditrex® to Request is for Otrexup™, Rasuvo® or Reditrex®, Jylamvo®. 7. Initial Approval Criteria, I.C.2: Updated request criteria from Request is for Xatmep® to Request is for Xatmep® and Jylamvo. 8. Initial Approval Criteria, I.C.3: Updated to include Brand methotrexate oral solution (Jylamvo®) age criteria Age ≥ 18 years. 9. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Mycosis fungoides. 10. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Relapsed or refractory non-Hodgkin lymphoma. 11. Continued Therapy Approval, II.A.4.c: Updated to include new dosing criteria for indication: <ol style="list-style-type: none"> a. Mycosis fungoides: 75 mg once weekly as monotherapy or 10 mg/m² twice weekly as combination chemotherapy; b. Relapsed or refractory non-Hodgkin lymphoma: 10 mg/week. 12. Appendix C, Contraindications: Updated to include new Brand Jylamvo® contraindication Pregnant patients with non-neoplastic diseases; history of severe hypersensitivity to methotrexate. 13. Appendix C, Boxed Warnings: Updated to include new Brand Jylamvo® boxed warning Embryo-fetal toxicity; history of severe hypersensitivity reactions to methotrexate, including anaphylaxis. 	
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	<p>14. Appendix D, Warnings and Precautions: Updated to include new Brand Jylamvo® warning and precaution Methotrexate suppresses hematopoiesis and can cause severe and life-threatening pancytopenia, anemia, leukopenia, neutropenia, and thrombocytopenia.</p>	
RxA.309.Xyrem_Xywav	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.2: Updated diagnostic criteria from Diagnosis has been confirmed through sleep lab evaluation [e.g., polysomnography and/or multiple sleep latency test (MSLT)];to Diagnosis has been confirmed through any one of the followings (a or b) <ol style="list-style-type: none"> a. sleep lab evaluation [e.g., polysomnography and/or multiple sleep latency test (MSLT)]; b. Lumbar puncture shows cerebrospinal fluid (CSF) hypocretin-1 level ≤ 110 pg/mL; 2. Initial Approval Criteria, I.A.5: Updated to remove trial and failure criteria for two antidepressants. 3. Initial Approval Criteria, I.B.5: Updated to remove amphetamine and dextroamphetamine immediate release and ER. 4. Initial Approval Criteria, I.B.6: Updated trial and failure criteria from Age ≥ 18 years, the member has tried and failed at least a one-month trial of armodafinil or modafinil, unless contraindicated or clinically significant adverse effects are experienced; to Age ≥ 17 years, the member has tried and failed at least a one-month trial of armodafinil or modafinil at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced. 5. Appendix B, Maximum Dose, protriptyline: Updated maximum dose information from 30 mg/day to 60 mg/day for all indication. 	04.01.2023
RxA.313.Prolia_Xgeva	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.2.a.iii: Updated to include new dosing criteria Recent osteoporotic fracture (within the past 12 months). 2. Initial Approval Criteria, I.A.2.b: Updated trial and failure criteria from Failure of a 12-month trial of an oral bisphosphonate (alendronate is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of a 3-year trial of bisphosphonate (alendronate is preferred), unless one of the following (i-v): <ol style="list-style-type: none"> i. All bisphosphonates are contraindicated; ii. Clinically significant adverse effects are experienced to both oral and IV formulations; iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy; iv. Member experienced an osteoporotic fracture or 	04.01.2023

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	<p>fragility fracture while receiving bisphosphonate therapy.</p> <ol style="list-style-type: none"> 3. Initial Approval Criteria, I.B.3: Updated to include new trial and failure criteria Trial and failure of zoledronic acid* (prostate or breast cancer) or pamidronate* (breast cancer) at up to maximally indicated doses unless both are contraindicated, or clinically significant adverse effects are experienced. *Prior authorization may be required. 4. Updated Multiple Myeloma or Solid tumour, Giant Cell Tumor of Bone and Hypercalcemia of Malignancy criteria to form separate criteria for each indication as I.C, I.D. and I.E. 5. Continued Therapy Approval Criteria, II.A.3.b: Updated dosing criteria from Xgeva®: 120 mg every 4 weeks to Xgeva®: 120 mg every 4 weeks or is supported by practice guidelines or peer reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) *Prescribed regimen must be FDA-approved or recommended by NCCN. 6. Appendix D, General Information: Updated to include new information IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects. 	
<p>RxA.361.Cotellic</p>	<ol style="list-style-type: none"> 1. Background: Updated to include new indication It is used as single agent for the treatment of adult patients with histiocytic neoplasms. 2. Dosing Information, Dosing Regimen, cobimetinib (Cotellic®): Updated dosing information from 60 mg orally once daily for 21 days, then off for 7 days (28-day cycle) to 60 mg (three tablets) orally once daily for 21 days give with vemurafenib 960 mg orally twice daily of a 28-day cycle until disease progression or unacceptable toxicity for indication Melanoma. 3. Dosing Information, Indication: Updated to include new indication Histiocytic neoplasms. 4. Dosing Information, Dosing Regimen, cobimetinib (Cotellic®): Updated to include dosing information for indication Histiocytic neoplasms. 5. Initial Approval Criteria, I.B.6.b.iv and I.B.6.b. v: Updated to include new diagnostic criteria: <ol style="list-style-type: none"> a. Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma; b. Oligodendroglioma. 6. Initial Approval Criteria, I.B.7.a and I.C.5.a: Updated to include new dosing criteria Dose does not exceed 60 mg per day, for the first 21 days of each 28- day cycle; 7. Initial Approval Criteria, I.B and I.C: Updated approval duration length from 6 months to 12 months for Commercial. 	<p>04.01.2023</p>

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	<p>8. Initial Approval criteria, I.C.2: Updated prescriber criteria from Prescribed by or in consultation with an oncologist to Prescribed by or in consultation with an oncologist or hematologist.</p> <p>9. Initial Approval Criteria, I.D and I.E: Updated to merge the Histiocytic Neoplasms- Erdheim-Chester Disease and Rosai-Dorfman Disease criteria into one as Histiocytic Neoplasms (I.C).</p>	
RxA.374.Erbitux	<p>1. Initial Approval Criteria, I.A.5: Updated combination therapy criteria from Prescribed as one of the following (a or b):</p> <ul style="list-style-type: none"> a. As a single agent; b. In combination with platinum-based therapy (e.g., cisplatin or carboplatin) with 5- FU; to Prescribed as one of the following (a or b or c): <ul style="list-style-type: none"> a. As a single agent; b. In combination with platinum-based therapy (e.g., cisplatin or carboplatin) with 5- FU; c. In combination with radiation therapy <p>2. Initial Approval Criteria, I.B.4.a: Updated indication from Disease is KRAS or NRAS wild-type to Disease is KRAS or NRAS wild-type or BRAF wild-type.</p> <p>3. Appendix D: Updated to include information about Braftovi.</p>	04.01.2023
RxA.376.Erleada	<p>1. Continued Therapy Approval Criteria, II.A.4: Updated to include new combination therapy criteria Member continues to use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy.</p>	04.01.2023
RxA.393.Imfinzi	<p>1. Background: Updated to include new indication:</p> <ul style="list-style-type: none"> a. In combination with tremelimumab-actl and platinum-based chemotherapy, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. b. In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC); c. In combination with tremelimumab-actl, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC). <p>2. Dosing Information, Indication: Updated to include new indication:</p> <ul style="list-style-type: none"> a. Metastatic NSCLC; b. BTC; c. uHCC. 	04.01.2023

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	<ol style="list-style-type: none"> 3. Dosing Information, Dosing Regimen and Maximum dose, durvalumab (Imfinzi®): Updated to include dosing information for indication Metastatic NSCLC, BTC and uHCC. 4. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of unresectable stage II- III NSCLC to Diagnosis of one of the following (a or b): <ol style="list-style-type: none"> a. Unresectable stage II- III NSCLC; AND <ol style="list-style-type: none"> i. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; b. Metastatic NSCLC and all of the following (i-iii): <ol style="list-style-type: none"> ii. Will be used in combination with tremelimumab-actl and platinum-based chemotherapy; iii. Member must have tumors that lack activating EGFR mutations and ALK fusion; iv. No prior chemotherapy or any other systemic therapy. 5. Initial Approval Criteria, I.A.4.b: Updated to include new dosing criteria Metastatic NSCLC: <ol style="list-style-type: none"> a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks; b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg IV every 4 weeks. 6. Initial Approval Criteria, I.C and I.D: Updated to include approval criteria for indication: <ol style="list-style-type: none"> a. Biliary Tract Cancer; b. Hepatocellular Carcinoma. 7. Continued Therapy Approval, II.A.4.b: Update to include new maximum dose criteria for Metastatic NSCLC <ol style="list-style-type: none"> a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks; b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg IV every 4 weeks. 8. Continued Therapy Approval, II.A.4.d: Updated to include new maximum dose criteria for BTC <ol style="list-style-type: none"> a. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy, then 20 mg/kg every 4 weeks as a single agent; b. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy, then 1,500 mg every 4 weeks as a single agent. 9. Continued Therapy Approval, II.A.4.e: Updated to include new maximum dose criteria for uHCC <ol style="list-style-type: none"> a. For body weight < 30 kg, new dose does not exceed 20 mg/kg on day 1 of cycle 1 in combination with 	
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	<p>tremelimumab followed by 20 mg/kg once every 4 weeks as a single agent;</p> <p>b. For body weight \geq 30 kg, dose does not exceed 1,500 mg on day 1 of cycle 1 in combination with tremelimumab followed by 1,500 mg once every 4 weeks as a single agent.</p>	
RxA.478.Signifor_Signifor. LAR	No update	04.01.2023
RxA.511.Turalio	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, pexidartinib (Turalio®): Updated dosing information from 400 mg orally twice daily on an empty stomach (at least one hour before or two hours after a meal or snack) until disease progression or unacceptable toxicity to 250 mg orally twice daily with a low-fat meal (approximately 11 to 14 grams of total fat) until disease progression or unacceptable toxicity for indication TGCT. 2. Dosing Information, Maximum Dose, pexidartinib (Turalio®): Updated to maximum dosing information From 800 mg/day to 500 mg/day for indication TGCT. 3. Dosing Information, Dosing Regimen, pexidartinib (Turalio®): Updated renal impairment dosing information from 200 mg in the morning and 400 mg in the evening to 125 mg in the morning and 250 mg in the evening with a low-fat meal. 4. Dosing Information, Dosing Regimen, pexidartinib (Turalio®): Updated to include hepatic impairment dosing information for indication TGCT. 5. Dosage Forms: Updated dosage form from Capsules: 200 mg to Capsules: 125 mg. 6. Initial Approval Criteria, I.A.5.a, I.B.5.a: Updated dosing criteria from Dose does not exceed 800 mg (4 capsules) per day to dose does not exceed 500 mg (4 capsules) per day. 7. Continued Therapy Approval Criteria, II.A.3.a: Updated dosing criteria from Dose does not exceed 800 mg (4 capsules) per day to dose does not exceed 500 mg (4 capsules) per day. 	04.01.2023
RxA.524.Trogarzo	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, ibalizumab-uiyk (Trogarzo®): Updated initial dosing information from a single loading dose of 2,000 mg IV, followed by a maintenance dose of 800 mg every 2 weeks to a single loading dose of 2,000 mg IV, followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% Sodium Chloride Injection, USP for indication HIV-1 infection. 2. Initial Approval Criteria, I.A.4: Updated documentation criteria from Documentation of 	04.01.2023

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	<p>resistance to at least one (1) antiretroviral agent from each of the four (4) classes (NRTI, NNRTI, PI, INSTI), unless contraindicated or clinically significant adverse effects are experienced to Documentation of resistance to at least one (1) antiretroviral agent from each of the three (3) classes (NRTI, NNRTI, PI), unless contraindicated or clinically significant adverse effects are experienced.</p> <ol style="list-style-type: none"> 3. Initial Approval Criteria, I.A.6: Updated trial and failure criteria to merge into one as "Trial and failure of one of the following, unless clinically significant adverse effects are experienced, both are contraindicated, or member is resistant to both: Fuzeon®, Selzentry® if CCR5 tropic." (I.A.5) 4. Appendix B, Drug Name: Updated to remove therapeutic alternatives: <ol style="list-style-type: none"> a. Tivicay®; b. Isentress®. 5. Appendix B, Drug Name: Updated to include generic therapeutic alternatives: <ol style="list-style-type: none"> a. emtricitabine; b. emtricitabine and tenofovir disoproxil fumarate. 	
RxA.531.Tymlos	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: "Diagnosis of osteoporosis" was replaced with Postmenopausal women with osteoporosis and one of the following (a or b); <ol style="list-style-type: none"> a. Member is at very high risk for fracture as evidenced by one of the following (i, ii, or iii): <ol style="list-style-type: none"> i. Recent osteoporotic fracture (within the past 12 months); ii. Bone mineral density (BMD) T-score at hip or spine ≤ -3.0; iii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus); b. Member has completed a 3-year trial of bisphosphonate therapy (see Appendix B; alendronate is preferred) at up to maximally indicated doses, unless one of the following (i-v): <ol style="list-style-type: none"> i. All bisphosphonates are contraindicated; ii. Clinically significant adverse effects are experienced to both IV and PO formulations (see Appendix D) iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy; iv. Member has experienced a lack of BMD increase after ≥ 12 months of 	04.01.2023

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	<p>bisphosphonate therapy;</p> <p>v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy; *Prior authorization may be required for bisphosphonates</p> <p>2. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria "Failure of a 12-month trial of a bisphosphonate (alendronate is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced".</p> <p>3. Initial Approval Criteria, I.A.5: Updated criteria pertaining to indication Osteoporosis Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®; Forteo®) that exceeds 2 years to Member has not received ≥ 2 years cumulative therapy on Tymlos®.</p> <p>4. Continued Therapy Approval, II.A.3: Updated criteria pertaining to indication Osteoporosis Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®; Forteo®) that exceeds 2 years to Member has not received ≥ 2 years cumulative therapy on Tymlos®.</p> <p>5. Appendix C, Boxed Warnings: Updated to remove boxed warnings;</p> <p>a. Risk of osteosarcoma;</p> <p>b. Cumulative use of Tymlos® and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient’s lifetime is not recommended.</p> <p>6. Appendix D, General Information: Updated to include new information regarding IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects.</p>	
RxA.594.Dupixent	<p>1. Background: Updated to include new indication prurigo nodularis (PN).</p> <p>2. Dosing Information, Indication: Updated to include new indication prurigo nodularis (PN).</p> <p>3. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, prurigo nodularis (PN).</p> <p>4. Continued Therapy Approval Criteria, II.E: Updated to include approval criteria for indication, prurigo nodularis (PN).</p> <p>5. Appendix B, Drug Name: Updated to remove discontinued Brand-name therapeutic alternative Diprolene® AF, Florone, Psorcon® E, Lidex®, Kenalog®, Decadron®, Deltasone®, Nasonex®.</p> <p>6. Appendix B, Drug Name: Updated to remove</p>	04.01.2023

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	<p>discontinued generic therapeutic alternative salmeterol.</p> <ol style="list-style-type: none"> 7. Appendix B, Dosing Regimen, dexamethasone: Updated to include adult dosing information 0.75 to 9 mg/day orally in 2 to 4 divided doses for indication Asthma. 8. Appendix B, Maximum Dose, dexamethasone: Updated maximum dose information from 16 mg/dose to Varies for indication asthma. 9. Appendix B, Dosing Regimen, methylprednisolone (Medrol®): Updated dosing information from 40 to 60 mg orally in 1 to 2 divided doses to 40 to 80 mg orally in 1 to 2 divided doses for indication Asthma. 10. Appendix B, Dosing Regimen, prednisolone (Millipred®, Orapred ODT®): Updated dosing information from 10 to 60 mg orally in 1 to 2 divided doses to 40 to 80 mg orally in 1 to 2 divided doses for indication Asthma. 	
RxA.611.Libtayo	<ol style="list-style-type: none"> 1. Background, NSCLC: Updated indication to include “As a single agent..”. 2. Background: Updated to include new indication In combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no EGFR, ALK or ROS1 aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic disease. 3. Initial Approval Criteria, I.C.6: Updated to include new diagnostic criteria Tumor has high PD-L1 expression (TPS ≥ 50%). 4. Initial Approval Criteria, I.C.7: Updated to include new criteria pertaining to indication NSCLC, Libtayo® will be used as one of the following (a or b): <ol style="list-style-type: none"> a. In combination with platinum-based chemotherapy for the first line treatment; b. As a single agent for the first-line treatment. 	04.01.2023
RxA.613.Oralair	No update	04.01.2023
RxA.618.Vyndamax_Vynd aqel	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.9: Updated to include new prescribing criteria Vyndaqel®/Vyndamax® is not prescribed concurrently with Onpattro® and Tegsedi®. 2. Continued Therapy Approval, II.A.3: Updated to include new prescribing criteria Vyndaqel®/Vyndamax® is not prescribed concurrently with Onpattro® and Tegsedi®. 3. Appendix D, General Information: Updated to include new information regarding concurrent use 	04.01.2023

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	of Onpattro® and Tegsedi®.	
RxA.620.Brukinsa	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, Brukinsa®: Updated to include hepatic impairment dosing information for indication MCL, MZL, WM. 2. Initial Approval Criteria, I.A.3 and I.C.3: Updated to remove prior contraindication criteria Member is intolerant to or have contraindications to ibrutinib. 3. Initial Approval Criteria, I.B.4 and I.C.5: Updated to include new prescribing criteria Brukinsa® is not prescribed concurrently with Imbruvica®. 4. Initial Approval Criteria, I.B.4.d: Updated to include new criteria pertaining to indication Waldenström’s Macroglobulinemia, For the management of symptomatic Bing-Neel syndrome. 5. Initial Approval Criteria, I.B.5.b and I.C.6.b: Updated to include new dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN. 6. Initial Approval Criteria, I.D.5: Updated to include new contraindication criteria Member has intolerance or contraindication to other BTK inhibitors (e.g., ibrutinib, acalabrutinib). 7. Continued Therapy Approval, II.A.3: Updated to remove therapy response criteria The prescriber has reassessed efficacy and established goals of therapy. 8. Appendix B, Drug Name: Updated to include therapeutic alternatives <ol style="list-style-type: none"> a. Calquence® b. Imbruvica® c. (bendamustine) Bendeka® + Rituxan® d. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + Rituxan® e. CVP (cyclophosphamide, vincristine, prednisone) + Rituxan® f. RCHOP/RICE (Rituxan®, cyclophosphamide, doxorubicin, vincristine, prednisone)/(Rituxan®, ifosfamide, carboplatin, etoposide) g. (bendamustine) Bendeka®/ Rituxan®, Imbruvica® +/- rituximab 9. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative <ol style="list-style-type: none"> a. rituximab b. CALGB (Rituxan®rituximab + methotrexate + cyclophosphamide, doxorubicin, 	04.01.2023

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	<p>vincristine, prednisone; etoposide, cytarabine, Rituxan®rituximab; carmustine, etoposide, cyclophosphamide/autologous stem cell rescue; Rituxan®rituximab).</p>	
<p>RxA.623.Givlaari</p>	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from The member has a diagnosis of AHP (including acute intermittent porphyria (AIP), hereditary coproporphyrinuria (HCP), variegate porphyria, or aminolevulinic acid (ALA) dehydratase deficient porphyria) to The member has a diagnosis of AHP (including acute intermittent porphyria (AIP), hereditary coproporphyrinuria (HCP), variegate porphyria, or aminolevulinic acid (ALA) dehydratase deficient porphyria) confirmed by one of the following (a or b); <ol style="list-style-type: none"> a. Genetic testing (i, ii, iii, or iv): <ol style="list-style-type: none"> i. AIP: positive HMBS (aka PBGD) mutation; ii. HCP: positive CPOX mutation; iii. VP: positive PPOX mutation; iv. ALAD porphyria: positive ALAD mutation; b. History of at least a four-fold increase of 5-aminolevulinic acid (ALA) or porphobilinogen (PBG) using a random urine sample within the past year (see Appendix D). 2. Initial Approval Criteria, I.A.5: “The member has active disease which is defined as two documented porphyria attacks within the past 6 months. These can include: <ol style="list-style-type: none"> i. Hospitalization; ii. Urgent healthcare visit; iii. IV hemin administration at home” was replaced with History of ≥ 2 porphyria attacks in a 6-month period requiring hospitalization, urgent healthcare visit, or IV Panhematin® (hemin for injection) administration at home, and (a or b): <ol style="list-style-type: none"> a. The porphyria attacks occurred within the last 6 months; b. The porphyria attacks occurred in any 6-month period, and member is currently receiving prophylactic Panhematin® therapy (e.g., once or twice a week on a regular basis). <p style="text-align: center;">*Prior authorization may be required.</p> 3. Continued Therapy Approval, II.A.2: “The member has responded positively to therapy with Givlaari® (e.g. reduction in hemin administration requirements, reduction in rate and/or number of porphyria attacks, improvement of signs and 	<p>04.01.2023</p>

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	<p>symptoms of AHP’s (e.g. pain, neurological, gastrointestinal, renal, quality of life etc.)” was replaced with Member is responding positively to therapy as evidenced by one of the following (a or b):</p> <ol style="list-style-type: none"> a. Decreased number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV Panhematin® administration at home; b. No increase in porphyria attacks requiring hospitalization, urgent healthcare visit, or IV Panhematin administration at home if member was receiving prophylactic Panhematin® therapy prior to Givlaari® initiation. <ol style="list-style-type: none"> 4. Approval duration: Commercial and Medicaid updated from 3 months to 6 months. 5. Appendix D, General Information: Updated to include new information regarding Concentrations of ALA or PBG in a random urine sample greater than four times the upper limit of normal establish the diagnosis of AHP. 	
RxA.625.Aklief	<ol style="list-style-type: none"> 1. Dosing Information, Maximum dose: Updated from not applicable to one application/day. 2. Initial Approval Criteria I.A.4: Updated from trial and failure of at least two (2) preferred topical anti-acne agents to trial and failure of one (1) topical anti-acne agents. 3. Initial Approval Criteria; Commercial and Medicaid approval duration updated from 6 months to 12 months. 4. Appendix B, Drug Name: Updated to include new therapeutic alternative tazarotene (Tazorac®). 	04.01.2023
RxA.626.Ayvakit	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.6.b and I.B.5.b: Updated to include new dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN. 2. Initial Approval Criteria, I.B.4: Updated prescriber criteria to include allergist, or immunologist. 3. Appendix A: Updated to include abbreviations MLNE and SM-AHN. 4. Appendix B, Dosing Regimen, imatinib mesylate (Gleevec®): Updated to include dosing regimen for indication MLNE. 	04.01.2023
RxA.627.Arazlo	<ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.3: Updated from trial and failure of two (2) preferred topical retinoid agents to trial and failure of one (1) topical retinoid agents. 	04.01.2023

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RxA.629.Tazverik	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.B.1: Updated to include diagnosis criteria Diagnosis of FL. 2. Appendix B, Drug Name: Updated to include new therapeutic alternative Follicular Lymphoma Examples of first-line, second-line and subsequent therapies: <ol style="list-style-type: none"> a. bendamustine + Gazyva® or rituximab b. CHOP (cyclophosphamide, doxorubicin, vincristine, predenison) + Gazyva® or rituximab c. CVP (cyclophosphamide, vincristine, prednisone) + Gazyva® or rituximab d. Revlimid® + Rituxan® e. Revlimid® + Gazyva® f. Single-agent examples: (Gazyva®; Revlimid®, Zydelig®, Copiktra®, Aliqopa®). 	04.01.2023
RxA.631.Xcopri	<ol style="list-style-type: none"> 1. Removed Appendix D: General Information. 	04.01.2023
RxA.655.LA_Injectable_An tipsychotics_Policy	<ol style="list-style-type: none"> 1. Dosing Information, Maximum Dose, olanzapine pamoate (Zyprexa® Relprevv™): Updated to maximum dosing information from 300 mg every 2 weeks to 300 mg every 2 weeks or 405 mg every 4 weeks for indication schizophrenia. 2. Dosing Information, Dosing Regimen, Invega Sustenna®: Updated to include renal impairment dosing information for indication Schizophrenia and Schizoaffective Disorder. 3. Initial Approval Criteria, I.A.8: Updated to include new dosing criteria Dose does not exceed any one of the following (a-h): <ol style="list-style-type: none"> a. Abilify Maintena®: 400 mg every 4 weeks; b. Aristada®: 882 mg monthly; c. Aristada Initio®: 675 mg one-time dose; d. Zyprexa® Relprevv™: 300 mg every 2 weeks or 405 mg every 4 weeks; e. Invega Trinza®: 819 mg every 3 months; f. Invega Sustenna®: 234 mg every 4 weeks; g. Risperdal Consta®: 50 mg every 2 weeks; h. Perseris®: 120 mg per month. 4. Initial Approval Criteria, I.B.7: Updated to include new dosing criteria Dose does not exceed any one of the following (a or b): <ol style="list-style-type: none"> a. Abilify Maintena®: 400 mg every 4 weeks; b. Risperdal Consta®: 50 mg every 2 weeks. 5. Initial Approval Criteria, I.C: Updated to include approval criteria for indication schizoaffective disorder. 6. Initial Approval Criteria I.A.4 and I.B.5 and I.C.5.a: Updated to remove requirement of history of non-adherence to oral anti-psychotics, based on 	04.01.2023

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	<p>reviewers’ feedback. Current practices and recommendation from prescribers and researchers in Schizophrenia and possibly other disorders now recommended LAIs to be offered at first visit.</p> <ol style="list-style-type: none"> 7. Continued Therapy Approval, II.A.3: Updated to include new dosing criteria If request is for dose increase, dose does not exceed any one of the following (a-h): <ol style="list-style-type: none"> a. Abilify Maintena®: 400 mg every 4 weeks; b. Aristada®: 882 mg monthly; c. Aristada Initio®: 675 mg one-time dose; d. Zyprexa® Relprevv™: 300 mg every 2 weeks or 405 mg every 4 weeks; e. Invega Trinza®: 819 mg every 3 months; f. Invega Sustenna®: 234 mg every 4 weeks; g. Risperdal Consta®: 50 mg every 2 weeks; h. Perseris®: 120 mg per month. 8. Continued Therapy Approval, II.B.3: Updated to include new dosing criteria If request is for dose increase, dose does not exceed any one of the following (a or b): <ol style="list-style-type: none"> a. Abilify Maintena®: 400 mg every 4 weeks; b. Risperdal Consta®: 50 mg every 2 weeks. 9. Continued Therapy Approval, II.C: Updated to include approval criteria for indication schizoaffective disorder. 	
<p>RxA.659.Kynmobi</p>	<ol style="list-style-type: none"> 1. Background: Updated indication from Kynmobi® is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of “off” episodes in patients with Parkinson’s Disease currently taking carbidopa/levodopa to Kynmobi® is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of “off” episodes in patients with Parkinson’s Disease. 2. Dosing Information, Indication: Updated from For the acute, intermittent treatment of “off” episodes in patients with Parkinson’s Disease currently taking carbidopa/levodopa to For the acute, intermittent treatment of “off” episodes in patients with Parkinson’s Disease. 3. Initial Approval Criteria, I.A.2: Updated diagnostic criteria from Documentation of number and frequency of “off” episodes to Member is experiencing “off” episodes such as muscle stiffness, slow movements, or difficulty starting movements. 4. Initial Approval Criteria, I.A.4: Updated to remove prior prescriber criteria "Dose initiation was or will be supervised by a healthcare provider". 	<p>04.01.2023</p>

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	<ol style="list-style-type: none"> 5. Initial Approval Criteria, I.A.4: Documentation that at least one (1) one other agent has been added to carbidopa/levodopa (e.g. dopamine agonist, COMT inhibitor, or MAO-B inhibitor) to reduce number and frequency of “off” episodes; was replaced with Member is currently receiving carbidopa/levodopa therapy; 6. Initial Approval Criteria, I.A.5: "Treatment with a concomitant antiemetic such as trimethobenzamide (not including 5HT3 antagonists) beginning 3 days prior to initial dose" was replaced with Member has previously tried one other treatment for “off” episodes (e.g., includes entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Apokyn, Ongentys, or Xadago, unless contraindicated or clinically side effects experienced. 7. Initial Approval Criteria, I.A.7: Updated combination therapy criteria from Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron) to Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron and alosetron). 8. Continued Therapy Approval, II.A.3: Updated combination therapy criteria from Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron) to Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron and alosetron). 9. Appendix B, Drug Name: Updated to include generic therapeutic alternative levodopa and apomorphine. 10. Appendix D, General Information: Updated to include new information regarding Concomitant use of apomorphine with drugs of the 5-HT3 antagonist class and Apomorphine induces nausea and vomiting. 	
<p>RxA.665.Bevacizumab</p>	<ol style="list-style-type: none"> 1. Background, Dosing information, Dosage Form, Clinical policy: Updated to include new drug Jylamvo®. 2. Initial Approval Criteria, I.H.1: Rephrased from Central nervous system cancer to Compendium Recommended Indications and added following indications: <ol style="list-style-type: none"> a. Ampullary adenocarcinoma-intestinal type; b. Endometrial carcinoma; c. Malignant peritoneal mesothelioma; d. Pediatric diffuse high-grade glioma; e. Primary central nervous system cancers; f. Small bowel adenocarcinoma; 	<p>04.01.2023</p>

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	<ul style="list-style-type: none"> g. Soft tissue sarcoma-solitary fibrous tumor or angiosarcoma; h. Vulvar cancer-squamous cell carcinoma <p>3. Initial Approval Criteria, I.H.4: Updated to remove prescribing criteria “Must be prescribed (a or b):</p> <ul style="list-style-type: none"> a. As a single agent or; b. In combination with carmustine, lomustine, or temozolomide if bevacizumab monotherapy fails and it is desirable to continue the steroid sparing effects of bevacizumab.” 	
RxA.666.Danyelza	1. Appendix B, Drug Name: Updated to include new therapeutic alternative cisplatin, etoposide, vincristine, cyclophosphamide, doxorubicin, topotecan, Unituxin®, isotretinoin, GM-CSF.	04.01.2023
RxA.667.Klisyri	No Update	04.01.2023
RxA.669.Tiglutik	1. Initial Approval Criteria, I.A.5: Updated to include new documentation criteria Documentation supporting member is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to age, oral/motor difficulties, or dysphagia.	04.01.2023
RxA.670.Zokinvy	No Update	04.01.2023
RxA.671.Chemotherapy_N OS	No update	04.01.2023
RxA.672.Margenza	<p>2. Dosing Information, Dosing Regimen, Margenza®: Updated dosing information from 15 mg/kg to 15 mg/kg IV every 3 weeks for indication metastatic HER2-positive breast cancer.</p> <p>3. Initial Approval Criteria, I.A.4.a: Updated prior therapy criteria from At least one prior therapy with anti-HER2-directed (e.g., ado-trastuzumab emtansine, lapatinib, neratinib, trastuzumab, pertuzumab) therapy to At least two prior therapy with anti-HER2-directed (e.g., ado-trastuzumab emtansine, lapatinib, neratinib, trastuzumab, pertuzumab) therapy.</p> <p>4. Initial Approval Criteria, I.A.7: Updated dosing criteria from Dose does not exceed FDA prescribing guidelines or dosing is supported by evidence-based guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN. to Request meets one of the following (a or b): *</p> <ul style="list-style-type: none"> a. Dose does not exceed 15 mg/kg IV every 3 weeks; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). 	04.01.2023

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	<p>*Prescribed regimen must be FDA approved or recommended by NCCN.</p> <p>5. Continued Therapy Approval Criteria II.A.3: Updated dosing criteria from If request is for a dose increase, dose does not exceed FDA prescribing guidelines or dosing is supported by evidence-based guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).</p> <p>*Prescribed regimen must be FDA-approved or recommended by NCCN.</p> <p>to If request is for a dose increase, request meets one of the following (a or b):*</p> <p>a. Dose does not exceed 15 mg/kg IV every 3 weeks;</p> <p>b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).</p> <p>*Prescribed regimen must be FDA-approved or recommended by NCCN.</p>	
<p>RxA.673.Rituximab</p>	<p>1. Initial Approval Criteria, I.D.5: Updated to remove prior trial and failure criteria "Member has failed at least one anti-TNF therapy (e.g., adalimumab, etanercept)."</p> <p>2. Initial Approval Criteria, I.D.6: Updated to include new trial and failure criteria For Ruxience®: Member meets one of the following (a or b):</p> <p>a. Trial and failure of at least two (2) of the following: Cimzia®, Enbrel®, Humira®, Simponi®, Rinvoq®, Xeljanz® or Xeljanz XR® unless contraindicated or clinically significant adverse effects are experienced or attestation demonstrating a trial may be inappropriate;</p> <p>b. Trial and failure of two TNF inhibitors: Cimzia®, Enbrel®, Humira®, Simponi®, Remicade®, Avsola®, Inflectra® or Renflexis®.</p> <p>3. Initial Approval Criteria, I.D.7: Updated to include new trial and failure criteria For Riabni™/Rituxan®/Truxima® request, member meets ALL of the following (a, b and c):</p> <p>a. Member meets one of the following (i or ii):</p> <p>i. Trial and failure of at least two (2) of the following: Cimzia®, Enbrel®, Humira®, Simponi®, Rinvoq®, Xeljanz® or Xeljanz XR® unless contraindicated or clinically significant adverse effects are experienced or attestation demonstrating a trial may be inappropriate;</p> <p>ii. Trial and failure of two TNF inhibitors:</p>	<p>04.01.2023</p>

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	<p>Cimzia®, Enbrel®, Humira®, Simponi®, Remicade®, Avsola®, Inflectra® or Renflexis®.</p> <p>b. Trial and failure, contraindication, or intolerance to BOTH of the following: Actemra® and Orenzia®;</p> <p>c. Trial and failure or intolerance to Ruxience®.</p>	
RxA.674.Trastuzumab	<ol style="list-style-type: none"> 1. Dosing Information, Maximum Dose, trastuzumab (Herceptin®); trastuzumab-pkrb (Herzuma®); trastuzumab-anns (Kanjinti™); trastuzumab-dkst (Ogivri®); trastuzumab-dttb (Ontruzant®); trastuzumab-qyyp (Trazimera®): Updated maximum dosing information from 8 mg/kg, 4 mg/kg, 8 mg/kg to Every-3-week dosing: 8 mg/kg IV initially, then 6 mg/kg IV every 3 weeks. Weekly dosing: 4 mg/kg IV initially, then 2 mg/kg IV every 2 weeks.for indication breast cancer. 2. Initial Approval Criteria, I.B.4, I.C.4, I.D.4, I.E.4, I.F.4: Updated to include new drug specific criteria The request for any one of the following: Herceptin®, Herzuma®, Kanjinti™, Ogivri®, Ontruzant®, Trazimera™. 3. Initial Approval Criteria, I.G: Updated to include approval criteria for indication, Hepatobiliary Cancers. 	04.01.2023
RxA.675.Orgovyx	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, relugolix (Orgovyx®): Updated to include specific information regarding combination dose for indication Advanced prostate cancer, Avoid use with combined P-gp and strong CYP3A inducers (e.g., rifampin). If unavoidable, increase Orgovyx® dose to 240 mg once daily. 2. Dosing Information, Maximum Dose, elugolix (Orgovyx®): Updated to include maximum dosing information for indication Advanced prostate cancer, Maintenance dose: 240 mg/day (if co-administration with combined P-gp and strong CYP3A inducers). 3. Initial Approval Criteria, I.A.1: Updated to remove diagnostic criteria “Diagnosis of castration-sensitive prostate cancer with documentation of (meets a and b): <ol style="list-style-type: none"> a. Serum testosterone levels; b. Serum PSA levels; 4. Initial Approval Criteria, I.A.1: Updated to diagnostic criteria Diagnosis of advanced prostate cancer defined as one of the following (a, b, or c): <ol style="list-style-type: none"> a. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with 	04.01.2023

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	<p>curative intent;</p> <p>b. Newly diagnosed castration-sensitive metastatic disease;</p> <p>c. Advanced localized disease unlikely to be cured by local primary intervention with curative intent</p> <p>5. Initial Approval Criteria, I.A.4.b: Updated to include new dosing criteria Dose does not exceed 360 mg on day 1, then 240 mg per day if combined with rifampin and combination use is unavoidable.</p> <p>6. Continued Therapy Approval, II.A.3.a: Updated dosing criteria from New dose does not exceed 360 mg on day 1, then 120 mg per day thereafter to New dose does not exceed 120 mg per day.</p> <p>7. Continued Therapy Approval, II.A.3.b: Updated to include new dosing criteria New dose does not exceed 240 mg per day if combined with rifampin and combination use is unavoidable.</p>	
RxA.676.Oxlumo	<p>1. Background: Updated indication from Oxlumo™ is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients to Oxlumo™ is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.</p> <p>2. Initial Approval Criteria, I.A.2: Updated to prescriber criteria to Endocrinologist and Hepatologist.</p> <p>3. Initial Approval Criteria, I.A.3: Updated to include new diagnostic criteria Documentation of one of the following (a or b):</p> <p>a. Urinary oxalate (UOx) excretion > 0.70 mmol/1.73 m² /24 h, confirmed on repeat testing;</p> <p>b. Spot urinary oxalate-to-creatinine (UOx:Cr) molar ratio greater than normal for age (see Appendix D for reference ranges), confirmed on repeat testing;</p> <p>4. Initial Approval Criteria, I.A.9: Updated dosing criteria from Requested dose does not exceed the FDA approved dosing recommendation to Dose does not exceed any of the following, based on body weight (a, b, or c):</p> <p>a. < 10 kg: 6 mg/kg per month for 3 doses followed by 3 mg/kg per month;</p> <p>b. 10 kg to < 20 kg: 6 mg/kg per month for 3 doses followed by 6 mg/kg every 3 months;</p>	04.01.2023

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	<ul style="list-style-type: none"> c. ≥ 20 kg: 3 mg/kg per month for 3 doses followed by 3 mg/kg every 3 months 5. Continued Therapy Approval Criteria, II.A.3: Updated to include documented improvement of plasma oxalate levels. 6. Continued Therapy Approval Criteria, II.A.5: Updated dosing criteria from Requested dose does not exceed the FDA approved dosing recommendation for continued therapy to If request is for a dose increase, new dose does not exceed any of the following, based on body weight (a, b, or c): <ul style="list-style-type: none"> a. < 10 kg: 3 mg/kg per month; b. 10 kg to < 20 kg: 6 mg/kg every 3 months; c. ≥ 20 kg: 3 mg/kg every 3 months. 7. Appendix D, General Information: Updated to include new information regarding Spot UOx/Cr Molar Ratio Reference Ranges in Spot Urine Samples. 	
RxA.703.Rylaze	<ul style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze®): Updated to include new dosing information for indication Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL). 2. Dosing Information, Maximum Dose, asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze®): Updated to include maximum dosing information for indication Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL). 3. Initial Approval Criteria, I.A.6.b: Updated to include new dosing criteria Dose does not exceed 50 mg/m² intramuscularly when administered on a Monday/Wednesday/Friday schedule (see dosing regimen). 4. Continued Therapy Approval, II.A.3.b: Updated to include new dosing criteria 50 mg/m² intramuscularly when administered on a Monday/Wednesday/Friday schedule (see dosing regimen). 5. Appendix B, Maximum dose, Oncaspar®: Updated maximum dose from Varies to <ul style="list-style-type: none"> a. Age 21 years and younger: 2,500 International Units/m² IV or intramuscular repeated no sooner than every 14 days; b. Age over 21 years: 2,000 International Units/m² IV or intramuscular repeated no sooner than every 14 days. 	04.01.2023
RxA.716.Brexafemme	<ul style="list-style-type: none"> 1. Background: Updated to include new indication Reduction in the incidence of recurrent 	04.01.2023

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	<p>vulvovaginal candidiasis (RVVC).</p> <ol style="list-style-type: none"> 2. Dosing Information, Indication: Updated to include new indication Recurrent vulvovaginal candidiasis (RVVC). 3. Dosing Information, Dosing Regimen, ibrexafungerp (Brexafemme®): Updated to include dosing information for indication Recurrent vulvovaginal candidiasis (RVVC). 4. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Recurrent vulvovaginal candidiasis (RVVC). 5. Continued Therapy Approval, II.B: Updated to include approval criteria for indication, Recurrent vulvovaginal candidiasis (RVVC). 6. Appendix B, Dosing Regimen, Oral fluconazole: Updated dosing information from: <ol style="list-style-type: none"> a. Uncomplicated: 150 mg orally as a single dose (FDA dosage); b. Complicated: Initial therapy 100 mg, 150 mg, or 200 mg oral dose of fluconazole every third day for a total of 3 doses (days 1, 4, and 7) is recommended, to attempt mycologic remission. c. Maintenance regimen: Oral fluconazole (100 mg, 150 mg, or 200 mg dose) weekly for 6 months is the indicated maintenance regimen to Vulvovaginal candidiasis (VVC): <ol style="list-style-type: none"> a. Uncomplicated: 150 mg orally as a single dose (FDA dosage); b. Complicated: 150 mg orally every 72 hours for 2 or 3 doses; c. Severe: 150 mg orally for 2 doses; give the second dose 72 hours after the first dose for indication Vulvovaginal candidiasis (VVC) and Recurrent vulvovaginal candidiasis (RVVC): <ol style="list-style-type: none"> a. 150 mg orally once weekly for at least 6 months following 10 to 14 days of induction therapy with a topical antifungal or oral fluconazole; b. Initial, 100 mg or 150 mg or 200 mg orally once weekly every third day for a total of 3 doses (days 1, 4, 7); c. Maintenance, 100 mg or 150 mg or 200 mg orally once weekly for 6 months for indication Recurrent vulvovaginal candidiasis (RVVC). 7. Appendix B, Maximum Dose, Oral fluconazole: Updated maximum dose information from: <ol style="list-style-type: none"> a. Uncomplicated: 150 mg; 	
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	<ul style="list-style-type: none"> b. Complicated: Initial therapy: 600 mg; c. Maintenance: 800 mg/week to a. Uncomplicated: 150 mg orally; b. Complicated/Severe: 150 mg per dose for indication Vulvovaginal candidiasis (VVC) and 200 mg orally once week for Recurrent vulvovaginal candidiasis (RVVC). <p>8. Appendix B, Drug Name: Updated to include new therapeutic alternative Vivjoa™.</p> <p>9. Appendix C, Boxed Warnings: Updated to include new boxed warning Risk of Embryo-Fetal Toxicity.</p>	
RxA.717.Nurtec.ODT	<ul style="list-style-type: none"> 1. Initial Approval Criteria I.A.7 and Continued Therapy Approval II.A.3: Updated to remove Ubrelvy®) as it is not indicated for migraine prophylaxis. 2. Initial Approval Criteria I.B.4 and Continued Therapy Approval II.B.4: Updated to remove Aimovig®, Ajovy®, Emgality®, Qulipta™, Vyepti as they are not indicated for acute treatment. 3. Duration for Initial Approval criteria for all indications updated to 6 months. 4. Duration for Continued Therapy Approval criteria for all indications updated to 12 months. 	04.01.2023
RxA.719.Besremi	<ul style="list-style-type: none"> 1. Initial Approval Criteria, I.A.3: Updated to include new prescriber criteria Prescribed by or in consultation with an oncologist or a hematologist. 2. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Failure of hydroxyurea at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced defined by one of the following(a-e): <ul style="list-style-type: none"> a. Need for phlebotomy to keep hematocrit less than 45% after 3 months on 2 g/day of HU; b. Platelet count >400 × 10⁹/L and white blood count >10 × 10⁹/L after 3 months on 2 g/day of HU; c. Reduction of splenomegaly <50% after 2 g/day of HU; d. Absolute neutrophil count <1.0 × 10⁹/L or platelet count <100 × 10⁹/L or hemoglobin <10 g/dL; e. Presence of hydroxyurea side effects at any dose of hydroxyurea to Trial and failure of hydroxyurea or peginterferon alfa-2a ,unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria, I.A.5: Updated to include 	04.01.2023

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	<p>new dosing criteria Documentation of JAK2 V617K mutation.</p> <ol style="list-style-type: none"> 4. Initial Approval Criteria, I.A.6: Updated to include new dosing criteria Member meets one of the following: <ol style="list-style-type: none"> a. For males: Documentation of hemoglobin level of at least 16.5 g/dL or hematocrit level of > 49% or increased red cell mass; b. For females: Documentation hemoglobin level of at least 16 g/dL or a hematocrit level of > 48% or increased red cell mass. 5. Initial Approval Criteria, I.A.7.b: Updated to include dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN. 6. Continued Therapy Approval, II.A.3.b: Updated to include dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN. 7. Appendix B, Drug Name: Updated to include Brand-name therapeutic alternative Pegasys®. 8. Appendix D, General Information: Updated to include new information regarding high risk PV patients preferred regimens for cytoreductive therapy as per NCCN. 	
RxA.720.Livtency	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, Livtency™: Updated to include co-administration information for indication post-transplant cytomegalovirus. 2. Dosing Information, Maximum Dose, Livtency™: Updated to maximum dosing information from 800 mg/day orally to 2,400 mg/day for indication post-transplant cytomegalovirus. 3. Initial Approval Criteria, I.A.7: Updated to include new diagnostic criteria Member does not have CMV disease involving the central nervous system (including the retina). 4. Initial Approval Criteria, I.A.9: Updated to include new dosing criteria Dose does not exceed (a, b, or c): <ol style="list-style-type: none"> a. 800 mg (4 tablets) per day; b. If co-administered with carbamazepine: 1,600 mg (8 tablets) per day; c. If co-administered with phenytoin or phenobarbital: 2,400 mg (12 tablets) per day. 5. Appendix B, Drug Name: Updated to include therapeutic alternatives: 	04.01.2023

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	<ul style="list-style-type: none"> a. valganciclovir (Valcyte®) b. foscarnet (Foscavir®) c. ganciclovir d. cidofovir <p>6. Appendix D: Updated to add Livtency™ may antagonize the antiviral activity of ganciclovir and valganciclovir. Coadministration is not recommended, based on reviewer’s feedback.</p> <p>7. Appendix D: Updated to add Livtency™ has the potential to increase the drug concentrations of immunosuppressant medications that are CYP3A4 and/or P-gp substrates (such as tacrolimus, cyclosporine, sirolimus and everolimus). Frequently monitor immunosuppressant drug levels is recommended throughout especially after initiation and after discontinuation of Livtency™.</p>	
RxA.721.Voxzogo	<ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen vorosoritide (Voxzogo®): “injection(subcutaneously): 0.4 mg, 0.56 mg, or 1.2 mg lyophilized powder in a single-dose vial for reconstitution” was replaced with weight-based dosing. 2. Initial Approval Criteria, I.A.5: “Patient has open epiphyses confirmed with imaging and a current AGV of ≥ 1.5 centimetres/year” was replaced with Current growth velocity ≥1.5 centimeters/year and documentation of one of the following (a or b): <ul style="list-style-type: none"> a. Tanner Stage <4; b. Recent imaging with evidence of open epiphyses. 3. Initial Approval Criteria I.A.8: Updated to add Voxzogo is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®); 4. Continued Therapy Approval Criteria II.A.4: “Patient has open epiphyses confirmed with imaging and a current AGV of ≥ 1.5 centimetres/year” was replaced with Current growth velocity ≥ 1.5 centimeters/year and documentation of one of the following (a or b): <ul style="list-style-type: none"> a. Tanner Stage <4; b. Recent imaging with evidence of open epiphyses. 	04.01.2023
RxA.730.Actemra	<ol style="list-style-type: none"> 1. Initial Approval Criteria I.C.5: Updated to add Xeljanz® in the trial and fail criteria. 2. Initial Approval Criteria I.A.5: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors 3. Initial Approval Criteria I.C.5: Updated to add *Trial 	04.01.2023

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	of Xeljanz® requires inadequate response to one or more TNF inhibitors.	
RxA.733.Cosentyx	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Rinvoq and added disclaimer "*Trial of Rinvoq®, Xeljanz®/XR®* requires inadequate response to one or more TNF inhibitors." 2. Initial Approval Criteria, I.A.6: Updated trial and failure criteria from For non-radiographic axial spondyloarthritis: Trial and failure of both Cimzia® and Taltz®, unless contraindicated or clinically significant adverse effects are experienced to For non-radiographic axial spondyloarthritis, member meets both (a and b): <ol style="list-style-type: none"> a. Trial and failure of all of Cimzia® and Rinvoq®*, unless contraindicated or clinically significant adverse effects are experienced; * Trial of Rinvoq® requires inadequate response to one or more TNF inhibitors b. Trial and failure of Taltz unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, I.C.4: Updated to include new disclaimer "*Trial of Rinvoq®, Xeljanz®/XR®* requires inadequate response to one or more TNF inhibitors." 	04.01.2023
RxA.735.Entyvio	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5: Updated trial and failure criteria to include new drug "Skyrizi™" and added exception "Exception: If a total of two TNF inhibitors has previously been tried and failed, trial of a third TNF inhibitor is not required." 2. Initial Approval Criteria, I.B.5: Updated trial and failure criteria from Trial and failure of at least two (2) of the following agents: Humira®, Simponi®, or Stelara® unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of at least two (2) of the following agents: Humira®, Rinvoq®*, Simponi®, Stelara®, Xeljanz®/XR*, unless contraindicated or clinically significant adverse effects are experienced; Exception: If a total of two TNF inhibitors has previously been tried and failed, trial of a third TNF inhibitor is not required.* Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors. 	04.01.2023
RxA.740.Olumiant	<ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.5.a: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors 2. Initial Approval Criteria I.C.7: Updated to remove 	04.01.2023

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	<p>Member has tried at least one of the following for alopecia areata (a or b):</p> <ol style="list-style-type: none"> Systemic therapies (e.g., corticosteroids, methotrexate, cyclosporine); Topical corticosteroids 	
RxA.741.Orencia	<ol style="list-style-type: none"> Initial Approval Criteria I.C.5: Updated to add Xeljanz® in the trial and fail criteria. Initial Approval Criteria I.C.5: Updated to add *Trial of Xeljanz® requires inadequate response to one or more TNF inhibitors. Initial Approval Criteria I.A.5 and I.B.4: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors. 	04.01.2023
RxA.745.Rinvoq	<ol style="list-style-type: none"> Background: Updated to include new indication Non-radiographic Axial Spondyloarthritis. Dosing Information, Indication: Updated to include new indication nr-axSpA. Initial Approval Criteria, I.E.: Updated from Ankylosing Spondylitis to Axial Spondyloarthritis. Initial Approval Criteria, I.E.1: Updated diagnostic criteria from Diagnosis of active ankylosing spondylitis (AS) to Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA). Initial Approval Criteria I.E.5: Updated to remove Trial and failure of at least one (1) of the following: Humira®, Cimzia®, Enbrel®, Simponi®/Simponi Aria®, unless contraindicated or clinically significant adverse effects are experienced. Continued Therapy Approval, II.A.3.a: Updated dosing criteria to include new indication nr-axSpA. Initial Approval Criteria, I.A.5 and I.B.4: Updated trial and failure criteria from Trial and failure of a ≥ 3 months of at least one (1) TNF inhibitor (Cimzia®, Humira®, Simponi®/ Simponi Aria, Enbrel®), unless contraindicated or clinically significant affects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. Initial Approval Criteria, I.D.5: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Humira®, Simponi®, unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. Appendix B, Dosing Regimen, NSAIDs, Cosentyx and Cimzia: Updated to include dosing information for indication nr-axSpA. 	04.01.2023

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RxA.748.Taltz	<ol style="list-style-type: none"> 1. Initial Approval Criteria I.C.4 and I.A.5.a: Updated to add Trial of Rinvoq®, Xeljanz®/XR®* requires inadequate response to one or more TNF inhibitors. 2. Initial Approval Criteria I.A .5.b: Updated to add Rinvoq®, as one of trial and failure drug and added that trial of Rinvoq®, requires inadequate response to one or more TNF inhibitors. 	04.01.2023
RxA.749.Xeljanz_Xeljanz XR	<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.6 and I.B.5: Updated trial and failure criteria from Trial and failure of a ≥ 3 months of at least one (1) TNF inhibitor (Cimzia®, Humira®, Simponi®/ Simponi Aria, Enbrel®), unless contraindicated or clinically significant affects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 2. Initial Approval Criteria, I.C.6: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Humira®, Enbrel®, Simponi®/ Simponi Aria®, Cimzia®, unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 3. Initial Approval Criteria, I.D.6: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Humira®, Simponi®, unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 4. Initial Approval Criteria, I.E.6: Updated trial and failure criteria from Trial and failure of Humira® and Enbrel® unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 	04.01.2023

New Step Therapy

- Acanya 1.2 %-2.5 % topical gel with pump
- Onexton 1.2 % (1 % base)-3.75 % topical gel
- Onexton 1.2 % (1 % base)-3.75 % topical gel with pump
- Benzaclin 1 %-5 % topical gel
- Twyneo 0.1 %-3 % topical cream
- Epiduo Forte 0.3 %-2.5 % topical gel with pump
- Ziana 1.2 %-0.025 % topical gel
- Benzaclin Pump 1 %-5 % topical gel
- Veltin 1.2 %-0.025 % topical gel
- Benzamycin 3 %-5 % topical gel

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- Mounjaro 2.5 mg/0.5 mL subcutaneous pen injector,
- Mounjaro 5 mg/0.5 mL subcutaneous pen injector,
- Mounjaro 7.5 mg/0.5 mL subcutaneous pen injector,
- Mounjaro 10 mg/0.5 mL subcutaneous pen injector,
- Mounjaro 12.5 mg/0.5 mL subcutaneous pen injector,
- Mounjaro 15 mg/0.5 mL subcutaneous pen injector

Updated Step Therapy

Drug Name; Strength(s); & Dosage Form(s)	Step Edit Details	Effective Date
Bydureon 2 mg subcutaneous ER suspension, Bydureon 2 mg/0.65 mL subcutaneous pen injector, Bydureon BCise 2 mg/0.85 mL subcutaneous auto-injector	ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro	04.01.2023
Byetta 10 mcg/dose (250 mcg/mL)2.4 mL subcutaneous pen injector, Byetta 5 mcg/dose (250 mcg/mL)1.2 mL subcutaneous pen injector	ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro	04.01.2023
Ozempic 0.25 mg or 0.5 mg (2 mg/1.5 mL) subcutaneous pen injector, Ozempic 1 mg/dose (2 mg/1.5 mL) subcutaneous pen injector, Ozempic 1 mg/dose (4 mg/3 mL) subcutaneous pen injector, Ozempic 2 mg/dose (8 mg/3 mL) subcutaneous pen injector	ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro	04.01.2023
Rybelsus 3 mg tablet, Rybelsus 7 mg tablet, Rybelsus 14 mg tablet	ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro	04.01.2023
Trulicity 0.75 mg/0.5 mL subcutaneous pen injector, Trulicity 1.5 mg/0.5 mL subcutaneous pen injector, Trulicity 3 mg/0.5 mL subcutaneous pen injector, Trulicity 4.5 mg/0.5 mL subcutaneous pen injector	ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro	04.01.2023

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<p>Victoza 2-Pak 0.6 mg/0.1 mL (18 mg/3 mL) subcutaneous pen injector, Victoza 3-Pak 0.6 mg/0.1 mL (18 mg/3 mL) subcutaneous pen injector</p>	<p>ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro</p>	<p>04.01.2023</p>
<p>Metformin 500 mg tablet, Metformin 850 mg tablet, Metformin 1,000 mg tablet, Metformin 500 mg/5 mL oral solution, Metformin ER 750 mg tablet, ER 24 hr, Metformin ER 500 mg tablet, ER 24 hr</p>	<p>ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro</p>	<p>04.01.2023</p>
<p>Glipizide 2.5 mg-metformin 250 mg tablet, Glipizide 2.5 mg-metformin 500 mg tablet, Glipizide 5 mg-metformin 500 mg tablet</p>	<p>ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro</p>	<p>04.01.2023</p>
<p>Glyburide 1.25 mg-metformin 250 mg tablet, Glyburide 2.5 mg-metformin 500 mg tablet, Glyburide 5 mg-metformin 500 mg tablet</p>	<p>ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro</p>	<p>04.01.2023</p>
<p>Pioglitazone 15 mg-metformin 500 mg tablet, Pioglitazone 15 mg-metformin 850 mg tablet</p>	<p>ST update Group name to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro</p>	<p>04.01.2023</p>
<p>Mounjaro 2.5 mg/0.5 mL subcutaneous pen injector, Mounjaro 5 mg/0.5 mL subcutaneous pen injector, Mounjaro 7.5 mg/0.5 mL subcutaneous pen injector, Mounjaro 10 mg/0.5 mL subcutaneous pen injector, Mounjaro 12.5 mg/0.5 mL subcutaneous pen injector, Mounjaro 15 mg/0.5 mL subcutaneous pen injector</p>	<p>ST Addition - Add Step-2 (target) drug to Existing ST Group AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza and re-name group to AMZ_Bydureon_BydureonBCISE_Byetta_Ozempic_Rybelsus_Trulicity_Victoza_Mounjaro</p>	<p>04.01.2023</p>

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