

## 4 Quarter 2022 Drug Formulary and Clinical Updates

Date of Notice: 12/01/2022

### Formulary Updates

Drug Name, Strength(s), & Dosage Form(s)	Description of Change	Formulary Status	Alternative Drug(s) (if applicable)	Effective Date
Amvuttra 25 mg/0.5 mL subcutaneous syringe (New Drug)	Formulary Addition	Non-Preferred Brand		01.01.2023
Emgality 120 mg/mL subcutaneous syringe, Emgality 120 mg/ml syringe	Formulary Update	Non-Preferred Brand		01.01.2023
Semglee U-100 Insulin 100 unit/mL subcutaneous solution, Semglee Pen U-100 Insulin 100 unit/mL (3 mL) subcutaneous, Semglee (insulin glargine-yfgn) 100 unit/mL subcutaneous solution Semglee (insulin glarg-yfgn) Pen 100 unit/mL (3 mL) subcutaneous insulin pen	Formulary Update	Preferred Brand		01.01.2023
Reyvow 50 mg tablet, Reyvow 100 mg tablet	Formulary Update	Non-Preferred Brand		01.01.2023
Pheburane 483 mg/gram oral granules (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		01.01.2023
Priorix (PF) 10exp3.4-4.2-3.3 CCID50/0.5 mL subcutaneous suspension (New Drug)	Formulary Addition; Age Based Copay Addition; ACA Master List Addition	Preventive medication		01.01.2023
Zoryve 0.3 % topical cream (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		01.01.2023
Calquence 100 mg capsule	QL Update	Preferred Brand		01.01.2023

### New Prior Authorization Policies

- RxA.775.Auvelity
- RxA.776.Pheburane
- RxA.777.Zoryve

### Updated Prior Authorization Policies

Policy Name	Policy Changes	Effective Date
RxA.003.Proton_Pump_Inhibitors	1. Dosing Information, Dosing Regimen, omeprazole magnesium granule (Prilosec®): Updated to include hepatic impairment dosing information for EE.	01.01.2023
RxA.004.Acticlate	No Update	01.01.2023
RxA.005.Atelvia	No Update	01.01.2023

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<p>RxA.007.Adempas</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.3: Updated from Member meets one of the following (i or ii);               <ol style="list-style-type: none"> <li>i. For PAH: Failure of a calcium channel blocker (see Appendix B), unless member meets one of the following (a or b):                   <ol style="list-style-type: none"> <li>a. Inadequate response or contraindication to acute vasoreactivity testing;</li> <li>b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced;</li> </ol> </li> <li>ii. For CTEPH: Disease is inoperable or persistent (i.e., suboptimal surgical outcome);</li> </ol> </li> <li>to Member meets one of the following (i or ii);               <ol style="list-style-type: none"> <li>i. For PAH: PAH is symptomatic AND (a or b):                   <ol style="list-style-type: none"> <li>a. Diagnosis of PAH was confirmed by right heart catheterization;</li> <li>b. Patient is currently on any therapy for the diagnosis of PAH;</li> </ol> </li> <li>ii. For CTEPH: CTEPH is symptomatic AND (a or b);                   <ol style="list-style-type: none"> <li>a. Diagnosis of inoperable or persistent/recurrent (i.e., suboptimal surgical outcome);</li> <li>b. Patient is currently on any therapy for the diagnosis of CTEPH;</li> </ol> </li> </ol> </li> <li>2. Appendix C, Boxed Warnings: Updated to include new boxed warning availability only through a REMS Program.</li> </ol>	<p>01.01.2023</p>
<p>RxA.008.Afinitor_Afinitor.D isperz_Zortress</p>	<ol style="list-style-type: none"> <li>1. Continued Therapy Criteria II.A.3.a: Updated new dose does not exceed from 20 mg to 10 mg per day</li> <li>2. Appendix B, Drug Name: Updated to include generic therapeutic alternative sorafenib tosylate.</li> </ol>	<p>01.01.2023</p>
<p>RxA.010.Aldurazyme</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.2: Updated to add Member has one of the following (a or b):               <ol style="list-style-type: none"> <li>a. Hurler or Hurler-Scheie form of MPS I;</li> <li>b. Scheie form of MPS I with moderate to severe symptoms</li> </ol> </li> </ol>	<p>01.01.2023</p>
<p>RxA.011.Aliqopa</p>	<ol style="list-style-type: none"> <li>1. Dosing Information, Dosing Regimen, copanlisib (Aliqopa®): Updated hepatic impairment dosing information from Reduce the Aliqopa® dose to 45 mg in patients with moderate hepatic impairment (Child-Pugh B) to Reduce the Aliqopa® dose to 45 mg in patients with moderate hepatic impairment (Child-Pugh B) or to 30 mg in patients with severe hepatic impairment (Child-Pugh C) for indication Relapsed follicular lymphoma.</li> <li>2. Appendix B, Drug Name: Updated to include generic therapeutic alternative lenalidomide.</li> <li>3. Appendix D, General Information: Updated to remove information regarding embryo-fetal toxicity</li> </ol>	<p>01.01.2023</p>

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<p>RxA.012.Alunbrig</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.B.5, I.C.4: Updated to add disease is ALK positive.</li> <li>2. Initial Approval Criteria I.B.6, I.C.6 , I.D.6: Updated from 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 to Requests meet one of the following (a or b):               <ol style="list-style-type: none"> <li>a. Dose does not exceed 180 mg per day;</li> <li>b. 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.</li> </ol> </li> <li>3. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Histiocytic Neoplasms.</li> </ol>	<p>01.01.2023</p>
<p>RxA.014.Apokyn</p>	<ol style="list-style-type: none"> <li>1. Dosing Information, Dosing Regimen, Apokyn: Updated dosing information from 0.2 mL (2mg) subcutaneous injection to 0.1 mL (1 mg) to 0.2 mL (2mg) subcutaneous injection for indication Parkinson's disease.</li> <li>2. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with a neurologist.</li> <li>3. Initial Approval Criteria, I.A.3: Updated to remove prior drug administration criteria "Dose initiation was or will be supervised by a healthcare provider."</li> <li>4. Initial Approval Criteria, I.A.4: Updated combination therapy criteria from Documentation that at least 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 to Prescribed concurrently with an anti-Parkinson agent (e.g., levodopa/carbidopa, dopamine agonists [e.g., ropinirole], catechol-O-methyl transferase [COMT] inhibitors [e.g., tolcapone], monoamine oxidase type B [MAO-B] inhibitors [e.g., rasagiline]).</li> <li>5. Initial Approval Criteria, I.A.5: Updated to remove prior combination therapy criteria "Treatment with a concomitant antiemetic such as trimethobenzamide (not including 5HT3 antagonists) beginning 3 days prior to initial dose."</li> <li>6. Initial Approval Criteria, I.A.6: Updated to remove prior combination therapy criteria "Member is not concurrently taking a 5HT3 antagonist (e.g. ondansetron)."</li> <li>7. Continued Therapy Approval Criteria, II.A.3: Updated to remove prior combination therapy criteria "Member is</li> </ol>	<p>01.01.2023</p>

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	<p>not concurrently taking a 5HT3 antagonist (e.g. ondansetron)."</p> <p>8. Appendix D, General Information: Updated to include new information regarding (a, b and c):</p> <ol style="list-style-type: none"> <li>a. Off time/episodes;</li> <li>b. Parkinson's disease symptoms;</li> <li>c. The addition of carbidopa to L-dopa.</li> </ol>	
RxA.015.Aralast NP_Glassia_Prolastin- C_Zemaira	No Update	01.01.2023
RxA.016.Arcalyst	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.2: Updated prescriber criteria from Prescribed by or in consultation with a rheumatologist to Prescribed by or in consultation with a rheumatologist, immunologist, allergist, dermatologist, neurologist or specialist with expertise in management of CAPS.</li> <li>2. Initial Approval Criteria, I.A.4: Updated to include new documentation criteria Documentation of one of the following (a or b): <ol style="list-style-type: none"> <li>a. For FCAS, classic signs and symptoms e.g., recurrent, intermittent fever and rash often exacerbated by exposure to generalized cool ambient temperature) AND functional impairment limiting activities of daily living;</li> <li>b. For MWS, classic signs and symptoms (e.g., chronic fever and rash of waxing and waning intensity, sometimes exacerbated with exposure to generalized cool ambient temperature) AND functional impairment limiting activities of daily living;</li> </ol> </li> <li>3. Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of deficiency of interleukin-1 receptor antagonist to Diagnosis of deficiency of interleukin-1 receptor antagonist confirmed by the presence of loss-of-function ILRN mutations.</li> <li>4. Initial Approval Criteria, I.B.3: Updated age criteria from Age <math>\geq</math> 18 years, or if age &lt; 18 years, member's body weight is <math>\geq</math> 10 kg to Weight is <math>\geq</math> 10 kg.</li> <li>5. Initial Approval Criteria, I.B.4: "If switching from another IL-1 blocker, the previous medication has been discontinued and Arcalyst® is started at the time of the next dose" replaced with "Member is in remission and has been stable for <math>\geq</math> 6 months".</li> <li>6. Initial Approval Criteria, I.C.1: Updated diagnostic criteria from Diagnosis of recurrent pericarditis to Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4-6 weeks apart.</li> </ol>	01.01.2023

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	<p>7. Initial Approval Criteria, I.C.4: Updated to include new trial and failure criteria Trial and failure of at least one of the following: non-steroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone), unless contraindicated or clinically significant adverse effects are experienced.</p> <p>8. Continued Therapy Approval Criteria, II.A.3: Updated response to therapy criteria from Member is responding positively to therapy to "Member has experienced disease stability or improvement in clinical symptoms while on therapy as evidenced by (a, b, c, d, e)..."</p> <p>9. Appendix D, General Information: Updated to remove information regarding Concomitant administration of Arcalyst® with tumor necrosis factor (TNF) inhibitors.</p> <p>10. Appendix D, General Information: Updated to include new information regarding (a and b):  a. DIRA patients;  b. Combination use of biological disease-modifying antirheumatic drugs.</p>	
RxA.017.Arikayce	No Update	01.01.2023
RxA.021.Accrufer	1. Initial Approval Criteria I.A.3: Updated to remove trial duration of 4 weeks	01.01.2023
RxA.022.Actimmune	No Update	01.01.2023
RxA.037.Benlysta	<p>1. Background: Updated information regarding indication lupus nephritis from Adult patients with active lupus nephritis (LN) who are receiving standard therapy to Patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.</p> <p>2. Background: Updated limitations of use from The efficacy of Benlysta® has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta® has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta® is not recommended in these situations to The efficacy of Benlysta® has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta® is not recommended in these situations.</p> <p>3. Initial Approval Criteria, I.B.2: Updated age criteria from Age ≥ 18 years to Age ≥ 5 years.</p> <p>4. Initial Approval Criteria, 1.B.3: Updated to include new prescriber criteria Prescribed by or in consultation with a nephrologist or a rheumatologist.</p> <p>5. Initial Approval Criteria, 1.B.4: Updated to remove prior diagnostic criteria "Member does not have severe active central nervous system lupus."</p> <p>6. Initial Approval Criteria, 1.B.5: Updated to remove prior</p>	01.01.2023

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	<p>combination therapy criteria “Member is not receiving Benlysta® in combination with other biologic agents or intravenous cyclophosphamide.”</p> <p>7. Initial Approval Criteria, I.B.6.b: Updated to include new dosing criteria Pediatrics (Age ≥ 5 years): Dose does not exceed 10 mg/kg/dose intravenously at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.</p> <p>8. Continued Therapy Approval Criteria, II.B.4.b: Updated to include new dosing criteria Pediatrics (Age ≥ 5 years): Dose does not exceed 10 mg/kg/dose intravenously.</p>	
RxA.054.Calquence	<p>1. Dosing Information, Maximum Dose, acalabrutinib (Calquence®): Updated maximum dosing information from 200 mg/day to 400 mg/day for indication MCL, CLL and SLL.</p> <p>2. Initial Approval Criteria I.A.1.: Updated diagnosis criteria from Diagnosis of MCL as a single-agent, second line therapy to Diagnosis of MCL.</p> <p>3. Initial Approval Criteria, I.A.7.a, I.B.5.a: Updated dosing criteria from dose does not exceed 200 mg (2 capsules) per day to dose does not exceed 400 mg per day.</p> <p>4. Initial Approval criteria I.A.6: Updated to include criteria for mutation “If refractory to Imbruvica® (member previously used Imbruvica and remission was not achieved or disease stopped responding), member does not have a BTK C481S mutation.”</p> <p>5. Initial Approval Criteria, I.D.5: Updated to include new prior treatment criteria Member has received ≥ 1 prior therapy.</p> <p>6. Initial Approval Criteria, I.C.5.a and I.D.6.a: Updated to include new dosing criteria dose does not exceed 400 mg per day.</p> <p>7. Continued Therapy Approval Criteria, II.A.3.a: Updated dosing criteria from new dose does not exceed 200 mg (2 capsules) per day to dose does not exceed 400 mg per day.</p> <p>8. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative acalabrutinib.</p> <p>9. Appendix B, Drug Name:</p> <ol style="list-style-type: none"> <li>a. updated to remove generic Ibrutinib and venetoclax as it is unavailable</li> <li>b. updated to include brand Imbruvica® and Venclexta®</li> </ol>	01.01.2023
RxA.074.Colonoscopy_Preparation_Products	<p>1. Drug(s) applied, Background, Dosing Information, Dosage forms, Clinical Policy, Appendix C was updated to remove information about Prepopik® as it is discontinued.</p>	01.01.2023

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<p>RxA.104.Diacomit</p>	<ol style="list-style-type: none"> <li>1. Background: Updated information regarding age from 2 years of age to 6 months of age.</li> <li>2. Background: Updated to include new information regarding patient's weight, "weighing 7 kg or more".</li> <li>3. Initial Approval Criteria, I.A.3: Updated age criteria from 2 years of age to 6 months of age.</li> <li>4. Initial Approval Criteria, I.A.4: Updated to include new weight criteria Member's weight <math>\geq</math> 7 kg.</li> <li>5. Appendix B, Maximum Dose, clobazam (Onfi®, Sympazan®): Updated maximum dose information from 0.5-2 mg/kg/day to 2 mg/kg/day for indication Seizures associated with Dravet syndrome.</li> </ol>	<p>01.01.2023</p>
<p>RxA.182.Krystexxa</p>	<ol style="list-style-type: none"> <li>1. Dosing Information, Dosing Regimen, Krystexxa®: Updated dosing information from 8 mg intravenously every 2 weeks to 8 mg intravenously every 2 weeks co-administered with weekly oral methotrexate 15 mg and folic acid or folinic acid supplementation.</li> <li>2. Initial Approval Criteria, I.A.8: Updated to include new prior treatment criteria Member has discontinued or will not institute therapy with oral urate-lowering agents while on Krystexxa® therapy.</li> <li>3. Appendix B, Drug name: Updated to include new therapeutic alternative Aloprim®</li> <li>4. Appendix C, Contraindications: Updated to include new contraindication History of serious hypersensitivity reactions, including anaphylaxis.</li> </ol>	<p>01.01.2023</p>
<p>RxA.216 Mekinist</p>	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors.</li> <li>2. Background: Updated to include limitation of use, "Mekinist® is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition."</li> <li>3. Dosing Information, Indication: Updated to include new indication BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors.</li> <li>4. Dosing Information, Dosing Regimen, Mekinist®: Updated to include dosing information for indication BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors.</li> <li>5. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors.</li> <li>6. Appendix D, General Information: Updated to include new information regarding Examples of solid tumors that may be BRAF V600E mutation-positive.</li> </ol>	<p>01.01.2023</p>
<p>RxA.289.Ultomiris</p>	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication generalized myasthenia gravis (gMG)</li> </ol>	<p>01.01.2023</p>

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	<ol style="list-style-type: none"> <li>2. Dosing Information, Indication: Updated to include new indication myasthenia gravis (gMG).</li> <li>3. Dosing Information, Dosing Regimen, Ultomiris®: Updated to include dosing information for indication gMG.</li> <li>4. Dosing Information, Maximum Dose, Ultomiris®: Updated to include maximum dosing information for indication gMG.</li> <li>5. Initial Approval Criteria, 1.A.5: Updated to include new prescriber criteria Ultomiris® is not prescribed concurrently with Empaveli™ or Soliris®.</li> <li>6. Initial Approval Criteria, I.B.6: Updated to include new diagnostic criteria Member has signs of TMA as evidenced by all of the following (a, b, and c):             <ol style="list-style-type: none"> <li>a. Platelet count <math>\leq 150 \times 10^9 /L</math>;</li> <li>b. Hemolysis such as an elevation in serum lactate dehydrogenase (LDH);</li> <li>c. Serum creatinine above the upper limits of normal or member requires dialysis</li> </ol> </li> <li>7. Initial Approval Criteria, I.C.: Updated to include approval criteria for indication, myasthenia gravis (gMG).</li> <li>8. Continued Therapy Approval Criteria, II.C.: Updated to include approval criteria for indication, myasthenia gravis (gMG).</li> <li>9. Appendix B, Drug Name: Updated to include therapeutic alternatives:             <ol style="list-style-type: none"> <li>a. betamethasone</li> <li>b. dexamethasone</li> <li>c. methylprednisolone</li> <li>d. prednisone</li> <li>e. pyridostigmine (Mestinon®, Regonol®)</li> <li>f. neostigmine (Bloxiverz®)</li> <li>g. azathioprine (Imuran®)</li> <li>h. mycophenolate mofetil (Cellcept®)</li> <li>i. cyclosporine (Sandimmune®)</li> <li>j. Rituxan®, Riabni™, Ruxience™, Truxima®</li> </ol> </li> </ol>	
<p>RxA.310.Xalkori</p>	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication inflammatory myofibroblastic tumor (IMT).</li> <li>2. Dosing Information, Indication: Updated to include new indication inflammatory myofibroblastic tumor (IMT).</li> <li>3. Initial Approval Criteria, I.A.5, I.B.3, I.C.3: Updated to include new prescribing criteria Prescribed as a single agent.</li> <li>4. Initial Approval Criteria, I.C.1: Updated indication from Diagnosis of ALK-positive inflammatory myofibroblastic tumor to Diagnosis of ALK-positive unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (a soft tissue sarcoma)</li> </ol>	<p>01.01.2023</p>

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	<ol style="list-style-type: none"> <li>5. Initial Approval Criteria, I.C.4: Updated age criteria from Age ≥ 18 years of age to Age ≥ 1 years of age.</li> <li>6. Initial Approval Criteria, I.D.4: Updated to include new criteria pertaining to indication, Histiocytic Neoplasms, Disease is ALK-positive.</li> <li>7. Initial Approval Criteria, I.D.5: Updated to include new criteria pertaining to indication, Histiocytic Neoplasms, Prescribed as a single agent.</li> <li>8. Appendix D, General Information: Updated to include new information regarding Dose adjustment for hepatic impairment and renal impairment.</li> </ol>	
RxA.334 Akynzeo	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.3 and Continued Therapy Criteria II.A.3: Updated to remove If request is for Akynzeo® capsules, Member continues to receive moderately to highly emetogenic cancer chemotherapy; (see Appendix D).</li> <li>2. Initial Approval Criteria I.A.4 and Continued Therapy Criteria II.A.4: Updated to remove If request is for Akynzeo® IV, member is scheduled to receive highly emetogenic cancer chemotherapy (see Appendix D).</li> </ol>	01.01.2023
RxA.489.Sernivo	No Update	01.01.2023
RxA.491.Soliris	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.D.1: Updated diagnostic criteria from Member has a clinically confirmed diagnosis of neuromyelitis optica spectrum disorder and is anti-aquaporin-4 antibody positive to Diagnosis of NMOSD.</li> <li>2. Initial Approval Criteria, I.D.2: Updated to include new lab test criteria Member has positive serologic test for anti-AQP4 antibodies.</li> <li>3. Initial Approval Criteria, I.D.8: Updated include new combination therapy criteria Soliris® is not prescribed concurrently with rituximab, Enspryng™, or Uplizna®.</li> <li>4. Initial Approval Criteria, I.D.7: Updated to remove prior combination therapy criteria Member is treated with eculizumab as monotherapy or in combination with or in combination with immunosuppressive therapy (i.e. azathioprine, mycophenolate or oral corticosteroids).</li> <li>5. Initial Approval Criteria, I.D.8: Updated to remove prior combination therapy criteria Member is not being treated with eculizumab for acute treatment of NMOSD relapse.</li> <li>6. Continued Therapy Approval Criteria, II.A.2, II.B.2: Updated to include new prescribing criteria Soliris is not prescribed concurrently with Ultomiris.</li> <li>7. Continued Therapy Approval Criteria, II.D.2: Updated to include new prescribing criteria Soliris® is not prescribed concurrently with rituximab, Enspryng, or Uplizna.</li> <li>8. Continued Therapy Approval Criteria II.D.3: Updated</li> </ol>	01.01.2023

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	<p>response to therapy criteria from Member is responding positively to therapy (i.e. increase in time to relapse of NMOSD is indicative of efficacy) to Member is responding positively to therapy-including but not limited to improvement or stabilization in any of the following parameters:</p> <ol style="list-style-type: none"> <li>Frequency of relapse;</li> <li>Expanded Disability Status Scale (EDSS);</li> <li>Visual Acuity.</li> </ol> <p>9. Appendix D, General Information: Updated to include new information regarding Ultomiris is a humanized monoclonal antibody to complement component...</p>	
RxA.492.Somatuline.Depot	<ol style="list-style-type: none"> <li>Initial Approval Criteria I.B.2: Updated to add endocrinologist as prescriber.</li> <li>Appendix D: Updated to add examples of Neuroendocrine and Adrenal tumors.</li> </ol>	01.01.2023
RxA.494.Spinraza	<ol style="list-style-type: none"> <li>Initial Approval Criteria I.A.2: Updated from Prescribed by or in consultation with a neurologist to add Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA.</li> <li>Initial Approval Criteria I.A: Approval duration updated from 4 doses to 6 doses.</li> </ol>	01.01.2023
RxA.495.Spritam	<ol style="list-style-type: none"> <li>Dosing Information, Maximum Dose, Spritam®: Updated to remove maximum dosing information for ages pediatric patients 4 years and older weighing 20 to 40 kg for indication Partial onset seizures and Primary generalized tonic-clonic seizures.</li> <li>Initial Approval Criteria, I.B.5.b: Updated dosing criteria from Primary generalized tonic-clonic seizures dose does not exceed 3,000 mg per day and 1,500 mg/day for adults and pediatric patients 6 years and older weighing 20 to 40 kg to Primary generalized tonic-clonic seizures: Dose does not exceed 3,000 mg/day for adults and pediatric patients ≥ 6 years and weighing &gt; 40 kg, 1500 mg for pediatric patients ≥ 6 years and weighing 20kg- 40 kg.</li> <li>Continued Therapy Approval Criteria, II.A.3.c: Updated dosing criteria from Primary generalized tonic-clonic seizures dose does not exceed 3,000 mg per day and 1,500 mg/day for adults and pediatric patients 6 years and older weighing 20 to 40 kg to Primary generalized tonic-clonic seizures: Dose does not exceed 3,000 mg/day for adults and pediatric patients ≥ 6 years and weighing &gt; 40 kg, 1500 mg for pediatric patients ≥ 6 years and weighing 20kg- 40 kg.</li> </ol>	01.01.2023
RxA.498.Strensiq	<ol style="list-style-type: none"> <li>Initial Approval Criteria and Continued Therapy Criteria: Updated to add note that patients requesting the 80 mg/0.8 mL vial only: Patient's weight is ≥ 40 kg.</li> </ol>	01.01.2023
RxA.500.Synagis	No Update	01.01.2023

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RxA.501.Syprine	No Update	01.01.2023
RxA.502.Tagrisso	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4: "Used as first-line therapy or used in adjuvant therapy after tumor resection." replaced with "Prescribed as a single agent."</li> <li>2. Initial Approval Criteria, I.A.5.a: Updated to include new request criteria a. Completely resected stage IB–IIIA EGFR mutation-positive NSCLC who received previous adjuvant chemotherapy or are ineligible to receive platinum based chemotherapy.</li> <li>3. Initial Approval Criteria, I.B.5.a: Updated dosing criteria from 160 mg (2 tablets) per day to Dose does not exceed 160 mg (2 tablets) per day if co-administered with a strong CYP3A4 inducer (e.g., phenytoin, rifampin, carbamazepine, St. John’s wort).</li> <li>4. Initial Approval Criteria, I.A, I.B, I.C: Updated approval duration criteria from 6 months to 12 months.</li> </ol>	01.01.2023
RxA.505.Tecfidera	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A: Commercial and Medicaid approval duration updated to 12 months.</li> </ol>	01.01.2023
RxA.506.Tegsedi	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria 1.A.6: Updated to remove ALT, AST, and total bilirubin should be in normal range (monitored within last month).</li> <li>2. Initial Approval Criteria I.A.8: Updated to remove member’s UPCR is less than 1,000 mg/g.</li> <li>3. Initial Approval Criteria I.A.6: Updated to add Member has not had a prior liver transplant.</li> <li>4. Initial Approval Criteria I.A.8: Updated to add Tegsedi is not prescribed concurrently with Onpattro™.</li> <li>5. Continued Therapy Criteria II.A.2: Updated to add Recent (dated within the last month) platelet count ≥ 100 x 10<sup>9</sup>/L.</li> </ol>	01.01.2023
RxA.508.Tibsovo	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4.a: Updated diagnostic criteria from Disease is newly diagnosed to Disease is newly diagnosed, prescribed in combination with azacitidine or as monotherapy.</li> <li>2. Initial Approval Criteria, I.A.4.c: "Disease has relapsed after or is refractory to induction therapy (see Appendix B for examples) was replaced with Age ≥ 60 years and one of the following (i or ii); <ol style="list-style-type: none"> <li>i. Member is not a candidate for intensive induction therapy;</li> <li>ii. Used for post-induction therapy with previous lower-intensity therapy (see Appendix B for examples) *.</li> </ol> </li> <li>3. Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of unresectable and metastatic cholangiocarcinoma to Diagnosis of locally advanced and metastatic cholangiocarcinoma.</li> <li>4. Initial Approval Criteria, I.B.2: Updated prescriber criteria from Prescribed by or in consultation with an</li> </ol>	01.01.2023

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	<p>oncologist or gastroenterologist to Prescribed by or in consultation with an oncologist, a hepatologist or a gastroenterologist.</p> <p>5. Appendix B, Drug Name: Updated to include therapeutic alternatives:</p> <ol style="list-style-type: none"> <li>gemcitabine + cisplatin;</li> <li>5-fluorouracil + oxaliplatin;</li> <li>capecitabine + cisplatin;</li> <li>5-fluorouracil;</li> <li>capecitabine;</li> <li>gemcitabine;</li> <li>FOLFOX (leucovorin, fluorouracil, oxaliplatin);</li> <li>FOLFIRI (leucovorin, fluorouracil, irinotecan);</li> <li>Stivarga®</li> </ol>	
RxA.509.Torisel	<ol style="list-style-type: none"> <li>Dosing information, Dosing regimen: Updated to add, Consider 50 mg once a week if concomitant strong CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital).</li> <li>Dosing information, Dosing regimen: Updated from 25 mg/week to 50 mg/week.</li> </ol>	01.01.2023
RxA.510.Trulance	No Update	01.01.2023
RxA.511.Turalio	<ol style="list-style-type: none"> <li>Dosing Information, Drug Regimen: Updated to add Reduce the dose of Turalio if used concomitantly with moderate/strong CYP3A inhibitors or UGT inhibitors.</li> <li>Initial Approval Criteria I.A.2, I.B.2: Updated to add prescriber criteria hematologist.</li> </ol>	01.01.2023
RxA.513.Takhzyro	<ol style="list-style-type: none"> <li>Dosing Information, Dosing Regimen: Updated to add, A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.</li> <li>Initial Approval Criteria I.A.2: Updated to add prescriber criteria, physician who specializes in the treatment of HAE or related orders.</li> <li>Initial Approval Criteria I.A.5 and Continued Therapy Criteria II.A.3: Updated to add examples of other HAE prophylactic therapies Cinryze®, Haegarda®, Orladeyo™.</li> </ol>	01.01.2023
RxA.514.Talzenna	<ol style="list-style-type: none"> <li>Dosage Forms: Updated to include new dosage form, 0.5 mg and 0.75 mg.</li> <li>Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of locally advanced, or metastatic breast cancer to Diagnosis of recurrent and metastatic breast cancer.</li> <li>Initial Approval Criteria, I.A.6: Updated to include new prior treatment criteria Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Zejula®).</li> <li>Initial Approval Criteria, I.A.7.b: Updated to include new</li> </ol>	01.01.2023

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	<p>dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).</p> <p>5. Continued Therapy Approval Criteria, II.A.3.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.</p> <p>6. Appendix D, General Information: Updated to include new information regarding the use of consecutive PARP inhibitors.</p> <p>7. Appendix D, General Information: Updated to remove information regarding "NCCN recommended uses: Breast cancer, as a single agent for recurrent or stage IV (M1) HER2-negative, BRCA 1/2-germline mutated disease...".</p>	
RxA.515.Tasigna	<p>1. Initial Approval Criteria, I.C.4: Updated trial and failure criteria to include drug Sprycel®.</p> <p>2. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (off-label).</p>	01.01.2023
RxA.521.Tracleer	<p>1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from diagnosis of PAH to diagnosis of WHO Group 1 PAH.</p> <p>2. Initial Approval Criteria, I.A.4: Failure of a calcium channel blocker (see Appendix B), unless member meets one of the following (a or b):</p> <p>a. Inadequate response or contraindication to acute vasodilator testing;</p> <p>b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced was replaced with</p> <p>Request meets one of the following (a or b):</p> <p>a. PAH is symptomatic;</p> <p>b. Diagnosis of PAH that is confirmed by right heart catheterization.</p>	01.01.2023
RxA.522.Trelstar_Triptodur	<p>1. Initial Approval Criteria I.C, I.C.1 and Continued Therapy Criteria II.C: Updated to add term gender dysphoria.</p>	01.01.2023
RxA.524.Trogarzo	No update	01.01.2023
RxA.525.Tykerb	<p>1. Initial Approval Criteria, I.A.6: Updated to include new gender criteria If member is a premenopausal female, member has been treated with ovarian ablation or is receiving ovarian suppression (see Appendix D).</p> <p>2. Initial Approval Criteria, I.B.5: Updated to include new dosing criteria Prescribed as a single agent.</p> <p>3. Initial Approval Criteria, I.C.4: Updated previous treatment criteria Member had no previous treatment</p>	01.01.2023

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	<p>with a HER-2 inhibitor (e.g., trastuzumab, Kadcyła®, Perjeta®) to Member had no previous treatment with a HER-2 inhibitor (e.g., trastuzumab, Kadcyła®, Tykerb® Perjeta®).</p> <ol style="list-style-type: none"> <li>4. Initial Approval Criteria, I.C.5: Updated to include new combination therapy criteria Prescribed in combination with trastuzumab.</li> <li>5. Initial Approval Criteria, I.C.6: Updated dosing criteria from Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence) to Request meets one of the following (a or b):             <ol style="list-style-type: none"> <li>a. Dose does not exceed 1500 mg/day;</li> <li>b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).</li> </ol> </li> <li>6. Initial Approval Criteria, I.D.3: Updated to include new combination therapy criteria to Prescribed in combination with capecitabine.</li> <li>7. Initial Approval Criteria, I.D.3: Updated to remove prior criteria pertaining to indication Central Nervous System (CNS) Cancers (off label), "Tykerb® will be approved if member meets all of the following (a, b or c):             <ol style="list-style-type: none"> <li>a. Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions;</li> <li>b. Tykerb® is active against primary (breast) tumor;</li> <li>c. Used in combination with capecitabine.</li> </ol> </li> <li>8. Initial Approval Criteria, I.D.4: Updated to remove prior criteria pertaining to indication Central Nervous System (CNS) Cancers (off label), "Member is treated in combination with temozolomide for progression or recurrent disease in patients who are refractory to surgery or radiation therapy (RT), if received prior RT and any of the following (a, b or c):             <ol style="list-style-type: none"> <li>a. Gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology;</li> <li>b. Subtotal resection and evidence of metastasis (brain, spine, or CSF);</li> <li>c. Unresectable disease.</li> </ol> </li> </ol>	
<p>RxA.526.Tafinlar</p>	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication unresectable or metastatic solid tumors with BRAF V600E mutation.</li> <li>2. Dosing Information, Indication: Updated to include new indication unresectable or metastatic solid tumors with BRAF V600E mutation.</li> <li>3. Initial Approval Criteria, I.A.5 and I.A.6: Updated prescriber criteria from Prescribed as a single agent for BRAF V600E mutation positive unresectable or</li> </ol>	<p>01.01.2023</p>

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	<p>metastatic melanoma; Prescribed in combination with trametinib for following; BRAF V600E or V600K Mutation-Positive Unresectable or Metastatic Melanoma; Adjuvant Treatment of BRAF V600E or V600K Mutation-Positive Melanoma to Prescribed as one of the following (a or b):</p> <ol style="list-style-type: none"> <li>a. In combination with Mekinist®;</li> <li>b. As a single agent for unresectable or metastatic disease with BRAF V600E mutation;</li> </ol> <ol style="list-style-type: none"> <li>4. Initial Approval Criteria, I.G: Updated to include approval criteria for indication, BRAF V600E Mutation-Positive Solid Tumor.</li> <li>5. Initial Approval Criteria, I.G: Updated to include approval criteria for indication, Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</li> <li>6. Continued Therapy Approval Criteria, II.A.3: Updated to include dosing criteria for BRAF V600E Mutation-Positive Solid Tumor.</li> <li>7. Appendix D, General Information: Updated to include new information regarding BRAF V600E Mutation-Positive Solid Tumor.</li> </ol>	
<p>RxA.527.Tavalisse</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5: Updated trial and failure criteria from Failure of systemic corticosteroids and immune globulins, unless contraindicated or clinically significant adverse effects are experienced (see Appendix B) to Member meets one if the following (a or b): <ol style="list-style-type: none"> <li>a. Trial and failure to a previous treatment (e.g , corticosteroids, immunoglobulins, thrombopoietin receptor agonists) unless contraindicated or clinically significant adverse effects are experienced (see Appendix B);</li> <li>b. Individual has undergone splenectomy;</li> </ol> </li> <li>2. Appendix D, General Information: Updated information regarding 2011 ASH guidelines to 2019 ASH guidelines.</li> </ol>	<p>01.01.2023</p>
<p>RxA.528.Tecentriq</p>	<ol style="list-style-type: none"> <li>1. Policy updated to remove indication Triple negative breast cancer.</li> <li>2. Background: Updated to remove detail(s) pertaining to indication UC, " Have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy ".</li> <li>3. Background: Updated to remove detail(s) pertaining to indication NSCLC, "Who have disease progression during or following platinum-containing chemotherapy. Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations should have disease progression on FDA</li> </ol>	<p>01.01.2023</p>

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	<p>approved therapy for these aberrations prior to receiving Tecentriq®”.</p> <ol style="list-style-type: none"> <li>4. Background: Updated to include detail(s) regarding indication NSCLC,             <ol style="list-style-type: none"> <li>a. “For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy”.</li> <li>b. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq”.</li> </ol> </li> <li>5. Dosing Information, Dosing Regimen, Tecentriq: Updated dosing information from 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks to 840 mg intravenous every 2 weeks, 1200 mg intravenous every 3 weeks, or 1680 mg intravenous every 4 weeks for indication UC.</li> <li>6. Dosing Information, Maximum Dose, Tecentriq: Updated to maximum dosing information from 840 mg/2 weeks to 1680 mg/4 weeks for indication Melanoma.</li> <li>7. Initial Approval Criteria, I.A.4.c: Updated to remove prior criteria pertaining to indication UC, " Disease has progressed during or following platinum-containing chemotherapy regardless of PD-L1 status.”</li> <li>8. Initial Approval Criteria, I.B.4: Updated combination therapy criteria from If EGFR or ALK mutation status is negative or unknown, member meets one of the following (a, b, c or d):             <ol style="list-style-type: none"> <li>a. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 <math>\geq</math> 50% [TC <math>\geq</math> 50%] or tumor-infiltrating IC covering <math>\geq</math> 10% of the tumor area [IC <math>\geq</math> 10%]);</li> <li>b. Disease is non-squamous, and Tecentriq® is prescribed in combination with one of the following (i or ii):                 <ol style="list-style-type: none"> <li>i. Bevacizumab, paclitaxel, and carboplatin;</li> <li>ii. Paclitaxel protein-bound (Abraxane®) and carboplatin;</li> </ol> </li> <li>c. Member has previously received platinum-containing chemotherapy (see Appendix B);</li> <li>d. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq® as well as nivolumab, pembrolizumab, durvalumab), request is for single agent as subsequent therapy to</li> </ol> <p>Member meets one of the following (a, b, or c):</p> <ol style="list-style-type: none"> <li>a. For stage II to IIIA NSCLC, prescribed as a single agent and meets one of the following (i or ii):</li> </ol> </li> </ol>	
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	<ul style="list-style-type: none"> <li>i. Member has had previous resection;</li> <li>ii. Member has all the following (a, b and c): <ul style="list-style-type: none"> <li>a) High-risk stage IIA NSCLC (see Appendix D);</li> <li>b) PD-L1 expression <math>\geq 1\%</math>;</li> <li>c) Previously received platinum-containing chemotherapy (see Appendix B)</li> </ul> </li> <li>b. If EGFR or ALK mutation status is negative or unknown, member meets one of the following (i, ii, iii or iv): <ul style="list-style-type: none"> <li>i. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 <math>\geq 50\%</math> [TC <math>\geq 50\%</math>] or tumor-infiltrating IC covering <math>\geq 10\%</math> of the tumor area [IC <math>\geq 10\%</math>]);</li> <li>ii. Disease is non-squamous, and Tecentriq® is prescribed in combination with one of the following (a or b): <ul style="list-style-type: none"> <li>a) Bevacizumab, paclitaxel, and carboplatin;</li> <li>b) Paclitaxel protein-bound (Abraxane®) and carboplatin;</li> </ul> </li> <li>iii. Member has previously received platinum-containing chemotherapy (see Appendix B);</li> <li>iv. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq® as well as nivolumab, pembrolizumab, durvalumab), request is for single agent as subsequent therapy;</li> </ul> </li> <li>c. If a known EGFR or ALK genomic tumor aberration is present, history of disease progression during or following an NCCN-recommended therapy for the aberration (see Appendix B);</li> </ul> <p>9. Initial Approval Criteria, 1.D.5: Updated to include new diagnostic criteria Confirmation of Child-Pugh class A status.</p> <p>10. Initial Approval Criteria, I.E.6: Updated to remove prior treatment criteria "Member must receive a 28 day treatment cycle of cobimetinib 60 mg orally once daily (21 days on and 7 days off) and vemurafenib 960 mg orally twice daily from Days 1-21 and vemurafenib 720 mg orally twice daily from Days 22-28) prior to initiating Tecentriq®."</p> <p>11. Initial Approval Criteria, I.E.6.a: Updated dosing criteria from 840 mg every 2 weeks with cobimetinib 60 mg orally once daily (21 days on /7 days off) and vemurafenib 720 mg orally twice daily to Dose does not exceed 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks.</p> <p>12. Initial Approval Criteria I.F: Updated to include new indication Peritoneal mesothelioma.</p> <p>13. Continued Therapy Approval Criteria II.A.3.b: Updated</p>	
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	<p>to remove prior dosing criteria "For Melanoma: 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks with cobimetinib 60 mg orally once daily (21 days on /7 days off) and vemurafenib 720 mg orally twice daily."</p> <p>14. Appendix B, Drug Name: Updated to include generic therapeutic alternative erlotinib HCl.</p> <p>15. Appendix D, General Information: Updated to include new information regarding NSCLC examples of high-risk factors.</p>	
RxA.530.Thyrogen	<p>1. Initial Approval Criteria, I.A.4.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.</p> <p>2. Initial Approval Criteria, II.A.4.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.</p>	01.01.2023
RxA.534.Valchlor	No Update	01.01.2023
RxA.540.Vecamyl	1. Appendix B, Drug Name: Updated to include generic therapeutic alternative nebivolol.	01.01.2023
RxA.541.Vectibix	<p>1. Initial Approval Criteria, I.A.4: Updated diagnostic criteria from Disease is wild-type RAS (defined as wild-type in both KRAS and NRAS) To Member meets one of the following (a or b):</p> <ol style="list-style-type: none"> <li>Disease is wild-type RAS (defined as wild-type in both KRAS and NRAS);</li> <li>BRAF wild-type.</li> </ol> <p>2. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative Braftovi®.</p>	01.01.2023
RxA.542.Velcade	No Update	01.01.2023
RxA.545.Ventavis	<p>1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of PAH to Diagnosis of PAH which is symptomatic.</p> <p>2. Initial Approval Criteria, I.A.3: "Failure of a calcium channel blocker (see Appendix B), unless member meets one of the following (a or b):</p> <ol style="list-style-type: none"> <li>Inadequate response or contraindication to acute vasodilator testing;</li> <li>Contraindication or clinically significant adverse effects to calcium channel blockers are experienced;" <p>was replaced with Member meets one of the following (a or b):</p> </li></ol>	01.01.2023

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	<ul style="list-style-type: none"> <li>a. Diagnosis of PAH was confirmed by right heart catheterization;</li> <li>b. Patient is currently on any therapy for the diagnosis of PAH</li> </ul>	
RxA.546.Verzenio	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score <math>\geq 20\%</math> as determined by an FDA approved test.</li> <li>2. Background: Updated information regarding indication Breast cancer to include men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.</li> <li>3. Background: Updated information regarding indication Breast cancer to include adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.</li> <li>4. Dosing Information, Dosing Regimen, Verzenio: Updated dosing information from In combination with fulvestrant or an aromatase inhibitor: 150 mg orally twice daily to In combination with fulvestrant, tamoxifen, or an aromatase inhibitor: 150 mg orally twice daily for indication Breast cancer.</li> <li>5. Initial Approval Criteria, I.A.4.b: Updated to include new combination therapy criteria *Men with breast cancer should be treated similarly to postmenopausal women, except that use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.</li> <li>6. Initial Approval Criteria, I.A.4.c: Updated to remove approval criteria for indication Advanced (locally recurrent) or metastatic.</li> <li>7. Initial Approval Criteria, I.A.5.e: Updated to include new diagnostic criteria For node-positive, early breast cancer with a high risk of recurrence, both of the following (i and ii): <ul style="list-style-type: none"> <li>i. As adjuvant treatment;</li> <li>ii. In combination with endocrine therapy (tamoxifen or an aromatase inhibitor);</li> </ul> </li> <li>8. Initial Approval Criteria, I.A.6: Updated to include new disease progression criteria Member has not previously experienced disease progression on a CDK 4/6 inhibitor therapy (e.g., Ibrance®, Kisqali®).</li> </ol>	01.01.2023

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	<p>9. Initial Approval Criteria, I.A.7: Updated to include new combination therapy criteria Verzenio® is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Ibrance, ® Kisqali®).</p> <p>10. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Verzenio® is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Ibrance, ® Kisqali®).</p> <p>11. Appendix B, Drug Name: Updated to include generic therapeutic alternative cyclophosphamide.</p>	
RxA.548.Viberzi	No Update	01.01.2023
RxA.549.Vidaza_Onureg	<p>1. Background: Updated to include new indication Juvenile Myelomonocytic Leukemia.</p> <p>2. Dosing Information, Maximum Dose, azacitidine (Vidaza®): Updated to include Dosing Regimen and maximum dosing information for indication JMML.</p> <p>3. Initial Approval Criteria, I.A.2 and I.E.3: Updated to include new drug request criteria Request is for Vidaza®.</p> <p>4. Initial Approval Criteria, I.A.4: Updated to remove prior criteria pertaining to indication MDS "Member meets one of the following (a, b, c, d, or e):</p> <ul style="list-style-type: none"> <li>a. With del(5q) cytogenetic abnormality: Failure of Revlimid® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization may be required for Revlimid®</li> <li>b. Without del(5q) cytogenetic abnormality and serum erythropoietin ≤ 500 mU/mL: Failure of Revlimid® and one of the following agents, unless all are contraindicated or clinically significant adverse effects are experienced: epoetin alfa (e.g., Epogen®, Procrit®, Retacrit™), Aranesp®; *Prior authorization may be required for Revlimid®, epoetin alfa (e.g., Epogen®, Procrit®, Retacrit™), and Aranesp®;</li> <li>c. Has previously received stem cell transplantation, will be receiving azacitidine as a bridge while awaiting stem cell transplant donor availability, or is not a candidate for stem cell transplant.</li> <li>d. Without del(5q) cytogenetic abnormality and serum erythropoietin &gt; 500 mU/mL.</li> <li>e. Clinically relevant (e.g., clinically severe) thrombocytopenia or neutropenia, or increased bone marrow blasts (see Appendix D)."</li> </ul> <p>5. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, JMML.</p> <p>6. Initial Approval Criteria, I.C.5 Updated to remove prior prescribing criteria "For Vidaza® requests, prescribed</p>	01.01.2023

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	<p>for one of the following (a, b, c or d):*</p> <ol style="list-style-type: none"> <li>a. In members age <math>\geq 60</math> years for one of the following (i, ii, or iii):             <ol style="list-style-type: none"> <li>i. As a single agent;</li> <li>ii. In combination with Nexavar® for FLT3-ITD mutation-positive disease;</li> <li>iii. In combination with Venclexta®;</li> </ol> </li> <li>b. Relapsed/refractory disease for one of the following (i, ii, iii or iv):             <ol style="list-style-type: none"> <li>i. As a component of repeating the initial successful induction regimen if late relapse (<math>\geq 12</math> months);</li> <li>ii. As a single agent;</li> <li>iii. In combination with Venclexta®;</li> <li>iv. In combination with Nexavar® for FLT3-ITD mutation-positive disease;</li> </ol> </li> <li>c. Treatment of myelofibrosis (MF)-accelerated phase or MF-blast phase/acute myeloid leukemia;</li> <li>d. Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) in combination with Venclexta®. *Prior authorization may be required for Nexavar® and Venclexta®.”</li> </ol> <p>7. Continued Therapy Approval Criteria, II.A.3.a and II.A.3.c: Updated to include new dosing criteria for drug:</p> <ol style="list-style-type: none"> <li>a. Onureg®;</li> <li>b. Vidaza® for JMML.</li> </ol> <p>8. Continued Therapy Approval Criteria, II.A.3.b: Updated dosing criteria from New dose does not exceed 100 mg/m<sup>2</sup> per day for 7 days per 4-week cycle to Vidaza® for MDS, AML, MF,(MDS)/(MPN): New dose does not exceed 100 mg/m<sup>2</sup> per day for 7 days per 4-week cycle.</p> <p>9. Appendix B, Drug Name: Updated to include generic therapeutic alternative lenalidomide.</p> <p>10. Appendix D, General Information: Updated to remove information regarding:</p> <ol style="list-style-type: none"> <li>a. The National Comprehensive Cancer Network (NCCN) guideline for MDS recommends the use of Vidaza® or Dacogen®.</li> <li>b. Vidaza® use for AML in elderly patients and for relapsed or refractory AML.</li> <li>c. RAEB-T has been reclassified as AML in WHO system.</li> <li>d. Revised International Prognostic Scoring System (IPSS) for MDS.</li> <li>e. National Comprehensive Cancer Network (NCCN) AML treatment guideline: No residual evidence of extramedullary disease.</li> </ol> <p>11. Appendix D, General Information: Updated to include new information regarding Hepatotoxicity, Renal</p>	
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	Toxicity, Tumor Lysis Syndrome and Embryo-Fetal Toxicity.	
RxA.550.ViekiraPak	<ol style="list-style-type: none"> <li>1. Dosing Information, Indication: Updated to remove indication Genotype 1a, with compensated cirrhosis.</li> <li>2. Dosing Information, Dosing Regimen, dasabuvir/ombitasvir/ paritaprevir/ritonavir(Viekira Pak®): Updated to remove dosing information for indication Genotype 1a, with compensated cirrhosis.</li> <li>3. Dosing Information, Dosing Regimen, Viekira Pak®: Updated to include specific information regarding dose, for indication HCV.</li> <li>4. Initial Approval Criteria, I.A.3: Updated prescriber criteria from Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease physician to Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease specialist or a liver transplant physician.</li> <li>5. Initial Approval Criteria, I.A.6: Updated trial and failure criteria from Member must use Harvoni® (brand preferred over generic) or Eplclusa® (brand preferred over generic) unless contraindicated or clinically significant adverse effects are experienced to Member must use Eplclusa® unless contraindicated or clinically significant adverse effects are experienced. *Coadministration with omeprazole up to 20 mg is not considered acceptable medical justification for inability to use Eplclusa.</li> <li>6. Initial Approval Criteria, 1.A.7: Updated to include new criteria pertaining to indication Chronic Hepatitis C Infection, Life expectancy ≥ 12 months with HCV treatment.</li> <li>7. Initial Approval Criteria, 1.A.8: Updated to include new Medication adherence program criteria: <ol style="list-style-type: none"> <li>a. Medication adherence monitored by pharmacy claims data or member report;</li> <li>b. Member’s risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks;</li> </ol> </li> <li>8. Initial Approval Criteria, 1.A.9: Updated to include new dosing criteria If HCV/HIV-1 co-infection, member is or will be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.</li> <li>9. Continued Therapy Approval, II.A.1.b.i: Updated documentation criteria from Documentation supports that member is currently receiving Viekira Pak® for chronic HCV infection and has recently completed at least three quarters of the full regimen with Viekira Pak® to Documentation supports that member is</li> </ol>	01.01.2023

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	<p>currently receiving Viekira Pak® for chronic HCV infection and has recently completed at least 60 days of treatment with Viekira Pak®.</p> <p>10. Appendix B, Drug Name: Updated to remove therapeutic alternatives:</p> <ol style="list-style-type: none"> <li>sofosbuvir/ledipasvir (Harvoni®),</li> <li>Mavyret®,</li> <li>Zepatier®.</li> </ol> <p>11. Appendix D: Updated to remove drugs daclatasvir, Olysio, simeprevir, Technivie*, ombitasvir, paritaprevir, ritonavir under Direct-Acting Antivirals for Treatment of HCV infection.</p> <p>12. Appendix E, General Information: Updated to include new information regarding Acceptable and Unacceptable medical justification for inability to use Eplusa.</p>	
RxA.551.Vimizim	1. Continued Therapy Approval II.A: Updated approval duration for commercial from 6 months to 12 months.	01.01.2023
RxA.552.Vimovo	1. Initial Approval Criteria, I.A.4: Updated combination therapy criteria from Medical justification supports inability to use the individual components (i.e., esomeprazole* and naproxen) concurrently (e.g., contraindications to the excipients of all brand and generic products) to Member must use the individual components (i.e., esomeprazole* and naproxen) concurrently, unless contraindicated to the excipients of all brand and generic products.	01.01.2023
RxA.554.Visudyne	1. Background: Updated to include limitation(s) of use, " There is insufficient evidence to indicate Visudyne® for the treatment of predominantly occult subfoveal CNV ".	01.01.2023
RxA.555.Vitrakvi	<p>1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of a solid tumor with both characteristics (a and b):</p> <ol style="list-style-type: none"> <li>Tumor is positive for NTRK-gene fusion;</li> <li>Disease is metastatic or surgical resection is likely to result in severe morbidity</li> </ol> <p>to Diagnosis of one of the following (a or b):</p> <ol style="list-style-type: none"> <li>Solid Tumor (see Appendix D for examples);</li> <li>Histiocytic neoplasm (e.g., Erdheim-Chester disease, Langerhans Cell histiocytosis, Rosai-Dorfman disease) (off-label).</li> </ol> <p>2. Initial Approval Criteria, I.A.2: Updated to remove prior diagnostic criteria " Disease has progressed following initial treatment or medical justification supports that there are no appropriate alternative treatments ".</p> <p>3. Initial Approval Criteria, I.A.3: Updated to include new diagnostic criteria Tumor is positive for an NRTK-gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1).</p> <p>4. Initial Approval Criteria, I.A.5: Updated to include new</p>	01.01.2023

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	<p>diagnostic criteria For solid tumor: Disease is persistent, recurrent, advanced, metastatic, unresectable, or resectable with adverse functional outcomes.</p> <p>5. Initial Approval Criteria, I.A.2: Updated prescriber criteria from Prescribed by or in consultation with an oncologist to Prescribed by or in consultation with one of the following (a or b):</p> <ol style="list-style-type: none"> <li>Oncologist;</li> <li>For Histiocytic neoplasm, a hematologist.</li> </ol> <p>6. Initial Approval Criteria, I.A.7: “Request meets one of the following (a, b or c):</p> <ol style="list-style-type: none"> <li>Dose does not exceed 200 mg/day;</li> <li>Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).” was replaced with Request meets one of the following (a, b or c):</li> </ol> <ol style="list-style-type: none"> <li>Adults and pediatric members with body surface area <math>\geq 1.0</math> m<sup>2</sup>: Dose does not exceed 200 mg per day;</li> <li>Pediatric members with body surface area <math>&lt; 1.0</math> m<sup>2</sup>: Dose does not exceed 200 mg/m<sup>2</sup> per day;</li> <li>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.</li> </ol> <p>7. Continued Therapy Approval Criteria, II.A.3.c: Updated to include new dosing criteria new 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.</p>	
RxA.556.Vivlodex	No Update	01.01.2023
RxA.557.Vizimpro	No Update	01.01.2023
RxA.558.Vosevi	No Update	01.01.2023
RxA.559.Votrient	No Update	01.01.2023
RxA.560.VPRIV	No Update	01.01.2023
RxA.562.Vyleesi	1. Initial Approval Criteria I.A: Commercial and Medicaid approval duration updated from 2 months from 3 months.	01.01.2023
RxA.564.Vyxeos	No Update	01.01.2023
RxA.567.Xhance	No Update	01.01.2023
RxA.568.Xpovio	No Update	01.01.2023

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RxA.569.Iluvien_Ozurdex_Retisert_Yutiq	No Update	01.01.2023
RxA.570.Zavesca	1. Initial Approval Criteria I.A.6 and Continued Therapy Criteria II.A.4: New dose does not exceed criteria updated from 600 mg to 300 mg daily.	01.01.2023
RxA.571.Zelboraf	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of unresectable or metastatic melanoma to Diagnosis of recurrent, lymph node positive, unresectable or metastatic melanoma.</li> <li>2. Initial Approval Criteria, I.A.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.</li> <li>3. Initial Approval Criteria, I.4.b: Updated to remove prior diagnostic criteria "Brain metastasis with a primary diagnosis of melanoma against which Zelboraf® was active".</li> <li>4. Initial Approval Criteria, I.5.a, b: Updated to remove prior combination therapy criteria "Request is to be considered as an adjuvant systemic therapy option in combination with cobimetinib for patients with a BRAF V600 activating mutation who have unacceptable toxicities to dabrafenib/trametinib, and member meets (a or b): <ol style="list-style-type: none"> <li>a. for resected stage III sentinel lymph node (SLN) positive disease during nodal basin ultrasound surveillance (preferred) or after completion lymph node dissection (CLND);</li> <li>b. for stage III disease with clinically positive node(s) following wide excision of primary tumor and therapeutic lymph node dissection (TLND)".</li> </ol> </li> <li>5. Initial Approval Criteria, I.6.a,b and c: Updated to remove prior combination therapy criteria "Preferred systemic therapy* option in combination with cobimetinib (or as a single agent if BRAF/MEK inhibitor combination therapy is contraindicated) for metastatic or unresectable disease** with a BRAF V600 activating mutation (a, b or c): <ol style="list-style-type: none"> <li>a. as first-line therapy;</li> <li>b. as second-line or subsequent therapy for disease progression if targeted therapy not previously used;</li> <li>c. may be considered as re-induction therapy for patients who experience disease control (complete response, partial response, or stable disease) and have no residual toxicity, but subsequently experience disease progression/relapse &gt;3 months after treatment discontinuation."</li> </ol> </li> </ol>	01.01.2023

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	<p>6. Initial Approval Criteria, I.7: Updated to remove prior combination therapy criteria "Systemic therapy* option in combination with cobimetinib and atezolizumab as first-line therapy for metastatic or unresectable disease** with a BRAF V600 activating mutation".</p> <p>7. Initial Approval Criteria, I.A.5.b: “*systemic therapy is preferred for unresectable metastatic disease **metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease was replaced with 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.</p> <p>8. Initial Approval Criteria, I.C.5: Updated trial and failure criteria from Failure of Tafinlar® and Mekinist® unless contraindicated or clinically significant adverse effects are experienced as (a or b); a. First-line therapy (useful in certain circumstances) b. Subsequent therapy following progression on first-line therapy with a non-BRAF-targeted regimen;* *Prior authorization may be required to Failure of Tafinlar® and Mekinist® unless contraindicated or clinically significant adverse effects are experienced.</p>	
RxA.573.Zejula	<p>1. Initial Approval Criteria I.A.4: Updated to remove Completed ≥ 2 platinum-based chemotherapy regimens and is in a complete or partial response.</p> <p>2. Appendix B: Updated to include altretamine (Hexalen®) as treatment alternative.</p>	01.01.2023
RxA.575.Zemplar	No Update	01.01.2023
RxA.577.Zolgensma	<p>1. Initial Approval Criteria, I.A.7.c: Updated to remove prior documentation criteria "Member does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence, tracheostomy, non-invasive ventilation beyond the use for sleep)."</p> <p>2. Initial Approval Criteria, I.A.9: Updated combination therapy criteria to include new drug Evrysdi®.</p> <p>3. Initial Approval Criteria, I.A.11: Updated to include new documentation criteria If the member is currently on Evrysdi®, must meet the following (a and b): a. Provider must submit evidence of clinical deterioration (e.g., sustained decrease in CHOP-INTEND score over a period of 3 to 6 months);</p>	01.01.2023

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	b. Documentation of provider attestation of clinical deterioration and Evrysdi® discontinuation.	
RxA.578.Zolinza	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.2: Updated to include new disease progression criteria Disease is progressive, persistent or recurrent on or following two systemic therapies (e.g., bexarotene, romidepsin, etc) unless contraindicated or clinically significant adverse effects are experienced.</li> <li>2. Initial Approval Criteria, I.A.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.</li> <li>3. Continued Therapy Approval Criteria, II.A.3.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.</li> <li>4. Appendix D, General Information: Updated to include new information regarding Chronic active EBV infection, Primary cutaneous peripheral T-cell lymphoma, NOS, Primary cutaneous acral CD8+ T-cell lymphoma.</li> </ol>	01.01.2023
RxA.579.Zulresso	<ol style="list-style-type: none"> <li>1. Background: Updated information regarding patients age from "adults" to "15 years and older."</li> <li>2. Initial Approval Criteria, I.A.1: "Diagnosis of major depressive disorder with postpartum onset based on DSM-IV criteria, defined as a major depressive episode with onset in the third trimester or within 4 weeks of delivery" was replaced with "Diagnosis of a major depressive episode that began no earlier than the third trimester and no later than the first 12 weeks following delivery, as diagnosed by Structured Clinical Interview for DSM-5."</li> <li>3. Initial Approval Criteria, I.A.3: Updated age criteria from Age 18 years of age or older to Age ≥ 15 years.</li> <li>4. Appendix B, Drug Name: Updated to include therapeutic alternatives. <ol style="list-style-type: none"> <li>a. amitriptyline (Elavil®)</li> <li>b. doxepin (Sinequan®)</li> <li>c. imipramine HCl (Tofranil®)</li> <li>d. imipramine pamoate (Tofranil PM®)</li> <li>e. protriptyline (Vivactil®)</li> <li>f. trimipramine (Surmontil®)</li> <li>g. Budeprion SR®, Budeprion XL</li> </ol> </li> <li>5. Appendix D, General Information: Updated information regarding HAM-D Score and PHQ-6 Score.</li> </ol>	01.01.2023
RxA.581.Zydelig	No Update	01.01.2023

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RxA.582.Zykadia	1. Initial Approval Criteria, I.A.4, I.B.5, I.C.4: Updated to include new prescribing criteria Prescribed as a single agent.	01.01.2023
RXA.585.Arzerra	1. Initial Approval Criteria I.A.4: Updated to add If request is for use as first line therapy, one of the following (a or b): a. Prescribed in combination with bendamustine, and there is no del(17)/TP53 mutation; b. Prescribed in combination with chlorambucil, and fludarabine-based therapy is considered inappropriate;	01.01.2023
RxA.586.Adakveo	1. Initial Approval Criteria I.A.6: Updated to add Failure of L-glutamine at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced. 2. Appendix B: Treatment alternatives updated to add information about L-glutamine.	01.01.2023
RxA.587.Aimovig	1. Appendix B, Maximum Dose, metoprolol (Lopressor®): Updated maximum dose information from 400 mg/day to 450 mg/day.	01.01.2023
RxA.588.Ajovy	1. Appendix B, Maximum Dose, metoprolol (Lopressor®): Updated maximum dose information from 200 mg/day to 450 mg/day. 2. Appendix B, Maximum Dose, amitriptyline: Updated maximum dose information from 100 mg/day orally to 150 mg/day orally in outpatients. 3. Appendix B, Maximum Dose, venlafaxine: Updated maximum dose information from 150 mg/day orally to 225 mg/day orally in outpatients.	01.01.2023
RxA.594.Dupixent	1. Background: Updated information regarding age for indication atopic dermatitis from "6 years and older" to "6 months and older". 2. Background: Updated to include new indication EoE. 3. Dosing Information, Dosing Regimen, Dupixent: Updated dosing information from Pediatric Patients (6 to 17 Years of Age): Body weight 15 to ≤ 30 kg : Initial dose of 600 mg subcutaneously followed by 300 mg subcutaneously every 4 weeks to Pediatric Patients (6 to 17 Years of Age): Body weight 15 to < 30 kg : Initial dose of 600 mg subcutaneously followed by 300 mg subcutaneously every 4 weeks for indication Moderate-to-severe atopic dermatitis 4. Dosing Information, Dosing Regimen, Dupixent: Updated to include dosing information for indication Moderate-to severe atopic dermatitis. 5. Dosing Information, Indication: Updated to include new indication EoE. 6. Initial Approval Criteria, I.A.3.: Updated age criteria from Age ≥ 6 years to Age ≥ 6 months.	01.01.2023

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	<p>7. Initial Approval Criteria, I.A.5.: Updated dosing criteria from Dose does not exceed the following (a or b):</p> <ul style="list-style-type: none"> <li>a. Initial (one-time) dose: 600 mg;</li> <li>b. Maintenance dose: 300 mg every other week.</li> </ul> <p>To Dose does not exceed the following (a, b or c):</p> <ul style="list-style-type: none"> <li>a. Age 6 months to 5 years and weight 5 to &lt; 15 kg: 200 mg every 4 weeks;</li> <li>b. Age 6 months to 5 years and weight 15 to &lt; 30 kg: 300 mg every 4 weeks;</li> <li>c. Age ≥ 6 years and the following (i or ii): <ul style="list-style-type: none"> <li>i. Initial (one-time) dose (1 or 2): <ul style="list-style-type: none"> <li>1. Age ≥ 18 years, weight ≥ 60 kg, or age 6-17 years and weight 15 to &lt; 30 kg: 600 mg;</li> <li>2. Age 6-17 years and weight 30 to &lt; 60 kg: 400 mg;</li> </ul> </li> <li>ii. Maintenance dose (1, 2 or 3): <ul style="list-style-type: none"> <li>1. Age ≥ 18 years or weight ≥ 60 kg: 300 mg every other week;</li> <li>2. Age 6-17 years and weight 30 to &lt; 60 kg: 200 mg every other week;</li> <li>3. Age 6-17 years and weight 15 to &lt; 30 kg: 300 mg every 4 weeks.</li> </ul> </li> </ul> </li> </ul> <p>8. Initial Approval Criteria, I.B.8.: Updated dosing criteria from Dose does not exceed the following (a or b):</p> <ul style="list-style-type: none"> <li>a. Initial (one-time) dose: 600 mg;</li> <li>b. Maintenance dose: 300 mg every other week to</li> </ul> <p>Dose does not exceed the following (a or b):</p> <ul style="list-style-type: none"> <li>a. Initial (one-time) dose for age ≥ 12 years: 600 mg;</li> <li>b. Maintenance dose (i, ii, or iii): <ul style="list-style-type: none"> <li>i. Age ≥ 12 years: 300 mg every other week;</li> <li>ii. Age 6-11 years and weight ≥ 30 kg: 200 mg every other week;</li> <li>iii. Age 6-11 years and weight 15 to &lt; 30 kg: 300 mg every 4 weeks.</li> </ul> </li> </ul> <p>9. Continued Therapy Approval Criteria II.A.3: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 300 mg given every other week to If request is for a dose increase, new dose does not exceed (a, b, c, d or e):</p> <ul style="list-style-type: none"> <li>a. Age ≥ 18 years or weight ≥ 60 kg: 300 mg every other week;</li> <li>b. Age 6-17 years and weight 30 to &lt; 60 kg: 200 mg every other week;</li> <li>c. Age 6-17 years and weight 15 to &lt; 30 kg: 300 mg every 4 weeks;</li> <li>d. Age 6 months to 5 years and weight 5 to &lt; 15 kg: 200 mg every 4 weeks;</li> <li>e. Age 6 months to 5 years and weight 15 to &lt; 30 kg: 300 mg every 4 weeks</li> </ul>	
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	<ol style="list-style-type: none"> <li>10. Initial Approval Criteria, I.D.: Updated to include criteria for new indication 'EoE'</li> <li>11. Continued Therapy Approval Criteria II.B.4: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 300 mg given every other week. To If request is for a dose increase, new dose does not exceed (a, b or c):             <ol style="list-style-type: none"> <li>a. Age ≥ 12 years: 300 mg every other week;</li> <li>b. Age 6-11 years and weight ≥ 30 kg: 200 mg every other week;</li> <li>c. Age 6-11 years and weight 15 to &lt; 30 kg: 300 mg every 4 weeks.</li> </ol> </li> <li>12. Continued Therapy Approval Criteria II.D.: Updated to include criteria for new indication 'EoE'.</li> <li>13. Appendix B, Dosing regimen, fluticasone/salmeterol (Advair®): Updated dosing regimen from Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation 1 actuation twice daily to Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation (1 actuation twice daily) HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation (2 actuation twice daily) for Asthma.</li> <li>14. Appendix B, Maximum Dose, fluticasone/salmeterol (Advair®): Updated maximum dose information from 1 actuation twice daily to Diskus: 1 actuation twice daily HFA: 2 actuation twice daily for indication Asthma.</li> <li>15. Appendix B, Drug Name: Updated to include therapeutic alternatives for indication EoE.             <ol style="list-style-type: none"> <li>a. Corticosteroids</li> <li>b. Proton pump inhibitors</li> </ol> </li> </ol>	
<p>RxA.595.Emgality</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Failure of an 8 week trial of at least two (2) of the following oral migraine preventative therapies, each from a different class, unless contraindicated or clinically significant adverse effects are experienced (a, b, or c):             <ol style="list-style-type: none"> <li>a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate);</li> <li>b. beta-blockers (e.g., metoprolol, propranolol, timolol);</li> <li>c. antidepressants (e.g., amitriptyline, venlafaxine) to Trial and failure of Aimovig® and Ajovy® unless contraindicated or clinically significant adverse effects are experienced;</li> </ol> </li> <li>2. Initial Approval Criteria, I.A.3: Updated to remove prior trial and failure criteria "Failure of verapamil at a dose of 360 mg per day, unless contraindicated or clinically significant adverse effects are experienced".</li> </ol>	<p>01.01.2023</p>

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	3. Appendix B, Maximum Dose, metoprolol (Lopressor®): Updated maximum dose information from 400 mg/day to 450 mg/day.	
RxA.597.Growth_Hormones	No Update	01.01.2023
RxA.601.Off-label_Use	No Update	01.01.2023
RxA.603.Glucose_Meter_Test_Strip_Exception_Policy	No Update	01.01.2023
RxA.604.Juxtapid	1. Initial Approval Criteria I.A.10: Updated to remove Kynamro® since it has been withdrawn from the market.	01.01.2023
RxA.605.Exondys51	<ol style="list-style-type: none"> <li>1. Continued Therapy Approval II.A.2.a: Updated to modify time frame for positive response parameters from within the last 30 days to within the last 6 months.</li> <li>2. Continued Therapy Approval II.A.2.b: Updated to add that member has received this medication via a health insurer without meeting the requirements in II.A.2.a and medical record shows improved or stable LVEF and FVC, assessed within the last 6 months.</li> <li>3. Continued Therapy Criteria II.A.3: Updated to add member has been assessed by a neurologist with in the last 6 months.</li> <li>4. Appendix D, Warnings and Precautions: Updated warning and precaution from Hypersensitivity reactions, including rash and urticaria, pyrexia, flushing, cough, dyspnea, bronchospasm, and hypotension, have occurred in patients who were treated with Exondys 51™ to Hypersensitivity reactions, including bronchospasm, chest pain, cough, tachycardia, and urticaria, have occurred in patients treated with Exondys 51™.</li> </ol>	01.01.2023
RxA.606.Jevtana	<ol style="list-style-type: none"> <li>1. Dosing Information, Indication: Updated from Prostate cancer to Castration-resistant prostate cancer (CRPC).</li> <li>2. Dosage Forms: Updated dosage form from Single-dose vial: 60 mg/1.5 mL to Single-dose vial: 60 mg/1.5 mL, supplied with diluent (5.7 mL) for Jevtana®.</li> <li>3. Initial Approval Criteria 1.A.7 and Continued Therapy Criteria II.A.4: Updated to include new combination therapy criteria Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy.</li> <li>4. Initial Approval Criteria II.A.3: Updated to add Jevtana® is prescribed concurrently with corticosteroid.</li> <li>5. Appendix D: Updated to include CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (&lt; 50 ng/dL). Per the NCCN, androgen deprivation therapy should be continued in the setting of CRPC while additional therapies are applied.</li> </ol>	01.01.2023

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RxA.607.Jublia	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.3: Added patients age <math>\geq</math> 18 years, trial and failure of a 12-week course of oral terbinafine at a maximum daily dose of 250 mg within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced.</li> <li>2. Continued therapy approval II.A.3: added member has not received more than 12 months of treatment with Jublia®.</li> <li>3. Continued therapy approval duration was updated to up to 12 months of total treatment from 12 months.</li> </ol>	01.01.2023
RxA.608.Lumizyme	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.3: Updated to include new combination therapy criteria Lumizyme® is not prescribed concurrently with Nexviazyme™.</li> <li>2. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Lumizyme® is not prescribed concurrently with Nexviazyme™.</li> </ol>	01.01.2023
RxA.610.Luzu	No Update	01.01.2023
RxA.615.Synribo	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4.b: Updated to include new trial and failure criteria Member has T315I mutation and has received prior treatment with Iclusig® and Scemblix®;</li> <li>2. Initial Approval Criteria, I.A.1.b: Updated to remove prior follow up therapy criteria "Member is receiving follow-up therapy after hematopoietic stem cell transplantation for either of the following: <ol style="list-style-type: none"> <li>i. Molecular relapse (BCR-ABL1 transcript positive) following a previous complete cytogenetic response;</li> <li>ii. Cytogenetic relapse or not in complete cytogenetic response;</li> </ol> </li> <li>3. Initial Approval Criteria, I.A.5.a: Updated dosing criteria from Dose does not exceed 2.5 mg/m<sup>2</sup> per day to Dose does not exceed 2.5 mg/m<sup>2</sup> per day for 14 consecutive days for induction and 7 consecutive days for maintenance of each 28-day cycle;</li> <li>4. Continued Therapy Approval Criteria, II.A.3.a: Updated dosing criteria from New dose does not exceed 2.5 mg/m<sup>2</sup> per day to New dose does not exceed 2.5 mg/m<sup>2</sup> per day for 14 consecutive days for induction and 7 consecutive days for maintenance of each 28-day cycle;</li> <li>5. Appendix B, Drug Name: Updated to include new therapeutic alternative: <ol style="list-style-type: none"> <li>a. imatinib (Gleevec®)</li> <li>b. bosutinib (Bosulif®)</li> <li>c. dasatinib (Sprycel®)</li> <li>d. nilotinib (Tasigna®)</li> <li>e. ponatinib (Iclusig®)</li> <li>f. asciminib (Scemblix®)</li> </ol> </li> </ol>	01.01.2023

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<p>RxA.616.Tarceva</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5, I.A.6: Updated to include new combination therapy criteria:               <ol style="list-style-type: none"> <li>a. Tarceva® may be prescribed as a single agent, in combination with Cyramza®, or in combination with bevacizumab;</li> <li>b. For use in combination with bevacizumab: Disease histology is nonsquamous NSCLC;</li> </ol> </li> <li>2. Initial Approval Criteria, I.A.7, I.B.5, I.C.5 &amp; I.D.5: Updated to include new trial and failure criteria For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced.</li> <li>3. Initial Approval Criteria, I.C.4: Updated to include new dosing criteria Prescribed as a single agent.</li> <li>4. Continued Therapy Approval Criteria, II.A.3: Updated to include new trial and failure criteria For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced.</li> </ol>	<p>01.01.2023</p>
<p>RxA.617.Venclexta</p>	<ol style="list-style-type: none"> <li>1. Appendix B: Updated to add therapeutic alternatives for multiple myeloma.</li> </ol>	<p>01.01.2023</p>
<p>RxA.619.Onpattro</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.8: Updated to include new combination therapy criteria Onpattro® is not prescribed concurrently with Tegsedi®.</li> </ol>	<p>01.01.2023</p>
<p>Rxa.628.Reblozyl</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.8: Updated to include criteria for transfusion history ‘Documentation of baseline transfusion burden within the last 6 months’.</li> <li>2. Initial Approval Criteria I.B.1: Updated diagnosis criteria from Diagnosis of anemia from very low- to intermediaterisk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) to Diagnosis of MDS-RS or MDS/MPNRS-T that meets one of the following classifications (a, b, or c) (see Appendix E):               <ol style="list-style-type: none"> <li>a. Very low, low, or intermediate risk as classified by IPSS-R;</li> <li>b. Low/intermediate-1 risk as classified by IPSS;</li> <li>c. Very low, low, or intermediate risk as classified by WPSS;</li> </ol> </li> <li>3. Initial Approval Criteria I.B.8: Updated to include criteria: Member does not have del(5q) cytogenetic abnormality.</li> <li>4. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative.               <ol style="list-style-type: none"> <li>a. Neupogen</li> <li>b. Nivestym</li> <li>c. Zarxio</li> </ol> </li> </ol>	<p>01.01.2023</p>

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	5. Appendix E: Added to include MDS risk classification.	
RxA.630.Ubrelvy	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.4: Updated to remove Member must currently be treated with one of the following preventative treatments, unless previously ineffective, contraindicated, or clinically significant adverse effects are experienced (a, b, or c):             <ol style="list-style-type: none"> <li>a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate);</li> <li>b. beta-blockers (e.g., metoprolol, propranolol, timolol);</li> <li>c. antidepressants (e.g., amitriptyline, venlafaxine);</li> </ol> </li> <li>2. Appendix B, Maximum Dose was updated:             <ol style="list-style-type: none"> <li>a. divalproex sodium (Depakote®): Updated maximum dose information from Level A (AAN; AHS) to 1,000 mg/day; Level A (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>b. divalproex sodium ER (Depakote® ER): Updated maximum dose information from Level A (AAN; AHS) to 1,000 mg/day; Level A (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>c. topiramate (Topamax®): Updated maximum dose information from Level A (AAN; AHS) to 100 mg/day; Level A (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>d. metoprolol (Lopressor®): Updated maximum dose information from Level A (AAN; AHS) to 200 mg/day; Level A (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>e. timolol: Updated maximum dose information from Level A (AAN; AHS) to 30 mg/day; Level A (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>f. atenolol (Tenormin®): Updated maximum dose information from Level B (AAN; AHS) to 100 mg/day; Level B (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>g. Updated maximum dose information from Level B (AAN; AHS) to 240 mg/day; Level B (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</li> <li>h. venlafaxine XR (Effexor XR®): Updated maximum dose information from Level B (AAN; AHS) to 225 mg/day; Level B (AAN; AHS) for indication acute</li> </ol> </li> </ol>	01.01.2023

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	<p>treatment of migraine with or without aura in adults.</p> <p>i. amitriptyline: Updated maximum dose information from Level B (AAN; AHS) to 150 mg/day; Level B (AAN; AHS) for indication acute treatment of migraine with or without aura in adults.</p> <p>3. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative</p> <p>a. erenumab</p> <p>b. fremanezumab</p> <p>c. galcanezumab</p>	
RxA.649.Zeposia	<p>1. Initial Approval Criteria, I.B.5: Updated trial and failure criteria to include drug Rinvoq® and Xeljanz/XR.</p>	01.01.2023
RxA.657.Gavreto	<p>1. Dosing Information, Maximum Dose, pralsetinib (Gavreto®): Updated to include maximum dosing information for indication Metastatic RET fusion positive NSCL and Thyroid cancer 800 mg/day with coadministration of strong CYP3A inducers.</p> <p>2. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of recurrent, advanced or metastatic disease with RET rearrangement positive tumors NSCLC to Diagnosis of recurrent, advanced or metastatic NSCLC.</p> <p>3. Initial Approval Criteria, I.A.4: Updated to remove prior diagnostic criteria "Member have an ECOG performance status of 0–1".</p> <p>4. Initial Approval Criteria, I.A.4: Updated to include new diagnostic criteria Member has RET fusion-positive disease (e.g., CCDC6-RET, KIF5B-RET).</p> <p>5. Initial Approval Criteria, I.A.5: Updated to remove prior diagnostic criteria "Member does not have another known mutation or primary driver alteration".</p> <p>6. Initial Approval Criteria, I.A.5: Updated prescribing criteria from Gavreto™ will be used as a single agent as first or subsequent line of therapy to Gavreto™ will be used as a single agent.</p> <p>7. Initial Approval Criteria, I.A.6 and I.B.5: Updated to include new combination therapy criteria Gavreto is not prescribed concurrently with Retevmo™.</p> <p>8. Initial Approval Criteria, I.A.7 and I.B.6: Updated to include prior therapy criteria Member has not received prior RET targeted therapy (e.g., Retevmo™).</p> <p>9. Initial Approval Criteria, I.A.8 and I.B.7: Updated dosing criteria from Requested dose does not exceed 400 mg orally once daily to Request meets one of the following (a, b, or c);</p> <p>a. Dose does not exceed 400 mg orally once daily;</p> <p>b. Dose does not exceed 800 mg daily and prescriber attestation of member’s inability to avoid</p>	01.01.2023

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	<p>concomitant use of CYP3A inducer (e.g., carbamazepine, rifampin, ritonavir, St. John’s wort);</p> <p>c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).</p> <p>10. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Gavreto is not prescribed concurrently with Retevmo™.</p> <p>11. Continued Therapy Approval Criteria, II.A.4: Updated to include prior therapy criteria Member has not received prior RET targeted therapy (e.g., Retevmo™).</p> <p>12. Continued Therapy Approval Criteria, II.A.5: Updated dosing criteria from Requested dose does not exceed 400 mg orally once daily to Request meets one of the following (a, b, or c);</p> <p>a. Dose does not exceed 400 mg orally once daily;</p> <p>b. Dose does not exceed 800 mg daily and prescriber attestation of member’s inability to avoid concomitant use of CYP3A inducer (e.g., carbamazepine, rifampin, ritonavir, St. John’s wort);</p> <p>c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).</p> <p>13. Continued Therapy Approval Criteria, II.A: Updated approval duration criteria from 6 months to 12 months.</p>	
RxA.660.Blenrep	<p>1. Initial Approval Criteria, I.A.3: Updated to include new prescribing criteria Prescribed as monotherapy.</p> <p>2. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Member has received at least four prior chemotherapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent to Member has received <math>\geq</math> four (4) prior that include all of the following (a, b, or c);</p> <p>a. One anti-CD38 monoclonal antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®);</p> <p>b. One proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®);</p> <p>c. One immunomodulatory agent (e.g., Revlimid®, pomalidomide, Thalomid®).</p> <p>3. Continued Therapy Approval Criteria, II.A.3: Updated to include new dosing criteria Dose is <math>\geq</math> 1.9 mg/kg every 3 weeks.</p> <p>4. Appendix B, Drug Name: Updated therapeutic alternatives listed from Velcade® to bortezomib (Velcade®).</p>	01.01.2023
RxA.662.Enspryng	<p>1. Initial Approval Criteria I.A.9 Updated to include new combination therapy criteria Enspryng is not prescribed concurrently with rituximab, Soliris®, or Uplizna®.</p>	01.01.2023
RxA.663.Evryssi	<p>1. Background: Updated information regarding age criteria</p>	01.01.2023

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	<p>from patients 2 months of age or older to in pediatric and adult patients.</p> <ol style="list-style-type: none"> <li>2. Dosing Information, Dosing Regimen, Evrysdi®: Updated to include dosing information for age group Less than 2 months of age.</li> <li>3. Initial Approval Criteria, I.A.2: Updated to remove prior age criteria.</li> <li>4. Initial Approval Criteria, I.A.3: Updated to include new criteria pertaining to indication Spinal Muscular Atrophy, Documentation of one of the following baseline scores (see Appendix D) (a or b):             <ol style="list-style-type: none"> <li>a. For age &lt; 2 years: Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score or Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score;</li> <li>b. For age ≥ 2 years: Hammersmith functional motor scale expanded (HF MSE) score, Revised Hammersmith Scale (RHS), Upper Limb Module (ULM), Revised Upper Limb Module (RULM), or 6-Minute Walk Test (6MWT);</li> </ol> </li> <li>5. Initial Approval Criteria, I.A.2: Updated diagnostic criteria from Patient is 2 years old or older to Genetic testing confirms the presence of one of the following (a, b, or c):             <ol style="list-style-type: none"> <li>a. Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);</li> <li>b. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7);</li> <li>c. Compound heterozygous mutation in the SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)].</li> </ol> </li> <li>6. Initial Approval Criteria, I.A.8: Updated to include new documentation criteria If the member is currently on Spinraza®, documentation of prescriber attestation of Spinraza® discontinuation upon initiation of Evrysdi®.</li> <li>7. Initial Approval Criteria, I.A.9: Updated to include new documentation criteria If the member has a history of treatment of Zolgensma®, provider must submit medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).</li> <li>8. Initial Approval Criteria, I.A.10: Updated dosing criteria from Dose does not exceed 5 mg daily. to Request meets one of the following (a, b, c, or d):             <ol style="list-style-type: none"> <li>a. If less than 2 months of age, dose does not exceed 0.15 mg/kg per day;</li> <li>b. If 2 months of age to less than 2 years of age, dose does not exceed 0.2 mg/kg per day;</li> </ol> </li> </ol>	
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	<ul style="list-style-type: none"> <li>c. If 2 years of age and older, weighing less than 20 kg, dose does not exceed 0.25 mg/kg per day;</li> <li>d. If 2 years of age and older, weighing 20 kg or more, dose does not exceed 5 mg per day.</li> <li>9. Continued Therapy Approval Criteria, II.A.2: Updated to include new criteria pertaining to indication Spinal Muscular Atrophy, Member does not require tracheostomy or invasive ventilation.</li> <li>10. Continued Therapy Approval Criteria, II.A.4: Updated to include new combination therapy criteria Evrysdi is not prescribed concurrently with Spinraza and/or Zolgensma.</li> <li>11. Appendix D, General Information: Updated to include new information regarding diagnostic baseline scores.</li> <li>12. Appendix D, General Information: Updated to remove information regarding treatment of SMA.</li> </ul>	
<p>RxA.664.Vyepti</p>	<ul style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.6: Updated trial and failure criteria from Failure of at least 1-month trial of one of the following unless member is allergic to any inactive ingredient of these drugs: Ajovy®, Aimovig®, or Emgality® to Trial and failure of Ajovy® and Aimovig® unless contraindicated or clinically significant adverse effects are experienced.</li> <li>2. Initial Approval Criteria, I.A.7: Updated combination therapy criteria from Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable CGRP inhibitors (e.g., (erenumab) Aimovig®, (fremanezumab) Ajovy®, (galcanezumab-gnlm) Emgality®) to Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable or oral CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Qulipta™, Ubrelvy™).</li> <li>3. Initial Approval Criteria, I.A.8: Updated to remove prior diagnostic criteria "Member shouldn't have any history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease".</li> <li>4. Continued Therapy Approval Criteria, II.A.3: Updated combination therapy criteria from Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable CGRP inhibitors (e.g., (erenumab) Aimovig®, (fremanezumab) Ajovy®, (galcanezumab-gnlm) Emgality®) to Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable or oral CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Qulipta™, Ubrelvy™).</li> <li>5. Appendix B, Drug name: Updated to include therapeutic alternative Emgality®.</li> </ul>	<p>01.01.2023</p>

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<p>RxA.673.Riabni</p>	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication Rheumatoid Arthritis for Riabni™.</li> <li>2. Dosing Information, Drug Name: Updated to include new drug Riabni™ for indication RA.</li> <li>3. Initial Approval Criteria, I.A.2, I.B.3, I.D.3, I.G.3: Updated to include new criteria Request is for Rituxan®/Riabni™/Ruxience®/Truxima®.</li> <li>4. Initial Approval Criteria, I.A.6, I.B.6 and I.C.5: Updated to include new combination therapy criteria Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors.</li> <li>5. Initial Approval Criteria, I.C.7.a: Updated dose criteria from Dose does not exceed 375 mg/m<sup>2</sup> intravenously to Dose for FDA approved indications does not exceed as mentioned in the dosing information.</li> <li>6. Initial Approval Criteria I.J.1: Updated to include new off-label indication Rosai-Dorfman Disease – Histiocytic Neoplasms.</li> <li>7. Continued Therapy Approval Criteria II.A.3: Updated dose 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 to Request meets one of the following (a or b)*:             <ol style="list-style-type: none"> <li>a. Dose does not exceed 1,000 mg intravenously per infusion;</li> <li>b. 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</li> </ol> </li> <li>8. Continued Therapy Approval Criteria II.B.4: Updated dose 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 to Request meets one of the following (a or b)*             <ol style="list-style-type: none"> <li>a. Dose does not exceed 375 mg/m<sup>2</sup> intravenously;</li> <li>b. 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</li> </ol> </li> <li>9. Continued Therapy Approval Criteria II.C.3: Updated dose 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 to If request is for a dose increase, dose does not exceed</li> </ol>	<p>01.01.2023</p>
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	<p>one of the following (a or b or c):*</p> <ul style="list-style-type: none"> <li>a. Dose for FDA approved indications does not exceed as mentioned in the dosing information;</li> <li>b. 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</li> </ul> <p>10. Continued Therapy Approval Criteria II.D.4: Updated dose 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. To If request is for a dose increase, dose does not exceed any one of the following (a or b):*</p> <ul style="list-style-type: none"> <li>a. Two-1,000 mg intravenous infusions every 16 weeks;</li> <li>b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use. *Prescribed regimen must be FDA-approved or recommended by NCCN</li> </ul>	
RxA.704.Exkivity	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5: Updated to remove prior diagnostic criteria "Patient's ECOG performance status is 0-1."</li> <li>2. Initial Approval Criteria, I.A.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).</li> <li>3. Continued Therapy Approval Criteria, II.A: Updated approval duration criteria from 6 months to 12 months.</li> <li>4. Appendix B, Dosing Regimen, erlotinib (Tarceva®), Iressa®, Gilotrif®, Tagrisso®, Vizimpro®: Updated to include dosing information for locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations.</li> <li>5. Appendix B, Maximum Dose, erlotinib (Tarceva®), Iressa®, Gilotrif®, Tagrisso®, Vizimpro®: Updated to include maximum dose information for locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations.</li> <li>6. Appendix B, Drug Name: Updated to include new therapeutic alternative Platinum-based chemotherapy (e.g., cisplatin, carboplatin).</li> <li>7. Appendix D, General Information: updated to remove information regarding ECOG performance status index score.</li> </ol>	01.01.2023
RxA.705.Tivdak	<ol style="list-style-type: none"> <li>1. Appendix B, Drug Name: Updated therapeutic alternatives listed from Avastin® to bevacizumab (Avastin®).</li> </ol>	01.01.2023

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	2. Appendix D, General Information: Updated to include new information regarding ECOG Status.	
RxA.707.Tyrvaya	<ol style="list-style-type: none"> <li>1. Appendix B, Drug name: Updated to remove unavailable generic therapeutic alternative hydroxypropyl cellulose.</li> <li>2. Appendix B, Drug Name: Updated therapeutic alternatives listed from Eysuvis™ to loteprednol etabonate (Eysuvis™) and Maxidex® to dexamethasone (Maxidex®).</li> <li>3. Appendix B, Maximum Dose, loteprednol suspension/gel (Lotemax®, Alrex®): Updated maximum dose-specific maximum dose information from Not Applicable to 8 drops/day loteprednol 0.25%, in each affected eye for indication Dry eye disease.</li> </ol>	01.01.2023
RxA.708.Korsuva	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.3: Updated to add Exclusion of other causes of pruritis (e.g eczema, infections, drug-induced skin dryness).</li> <li>2. Initial Approval Criteria I.A.3: Updated to remove member is receiving hemodialysis 3 times/week for at least 3 months.</li> </ol>	01.01.2023
RxA.709.Livmarli	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of cholestatic pruritus in patients with Alagille syndrome (ALGS) to Diagnosis of ALGS-associated pruritis with molecular genetic testing confirmed mutations in the JAG1 or NOTCH2 gene.</li> <li>2. Initial Approval Criteria, I.A.6: Updated to remove prior disease criteria "Patient does not have chronic diarrhea requiring ongoing intravenous fluid or nutritional intervention".</li> <li>3. Initial Approval Criteria, I.A.7: Updated to remove prior surgery criteria "No history of surgical interruption of enterohepatic circulation (for example, partial external biliary diversion [PEBD] surgery)".</li> <li>4. Initial Approval Criteria, I.A.8: Updated to remove prior disease criteria "No clinical evidence of decompensated cirrhosis".</li> <li>5. Initial Approval Criteria, I.A.6.b: Updated trial and failure criteria: Cholestyramine to Bile acid sequestrants (e.g., Questran, Colestid, Welchol, cholestyramine).</li> <li>6. Initial Approval Criteria, I.A.6.d: Updated to remove prior trial and failure criteria "Naltrexone".</li> <li>7. Initial Approval Criteria, I.A.6.e: Updated to remove prior trial and failure criteria "Sertraline".</li> <li>8. Initial Approval Criteria, I.A.6.d: Updated to include new trial and failure criteria Antihistamines (e.g., diphenhydramine, hydroxyzine).</li> <li>9. Initial Approval Criteria, I.A.7: Updated to include new diagnostic criteria Documentation of member's current weight in kilograms.</li> </ol>	01.01.2023

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	<ol style="list-style-type: none"> <li>10. Initial Approval Criteria, I.A.8: Updated dosing criteria from Requested dose does not exceed 28.5 mg/day orally to Requested dose does not exceed 380 mcg/kg per day up to a maximum of 28.5 mg (3 ml) per day.</li> <li>11. Initial Approval Criteria, I.A: Updated approval duration criteria from 6 months to 12 months.</li> <li>12. Continued Therapy Approval Criteria, II.A.3: Updated to include new diagnostic criteria Documentation of member's current weight in kilograms.</li> <li>13. Continued Therapy Approval Criteria, II.A.4: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 28.5 mg orally once daily to If request is for a dose increase, new dose does not exceed new dose does not exceed 380 mcg/kg per day, up to a maximum 28.5 mg (3 mL) per day.</li> <li>14. Appendix B, Drug Name: Updated to include therapeutic alternatives Antihistamines.</li> <li>15. Appendix D, General Information: Updated to remove information regarding Liver Test Abnormalities: Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be considered if abnormalities occur. For persistent or recurrent liver test abnormalities, consider Livmarli™ discontinuation.</li> <li>16. Appendix D, General Information: Updated to include new table regarding Classic Criteria, Based on Five Body Systems, for a Diagnosis of ALGS.</li> </ol>	
<p>RxA.710.Loreev XR</p>	<ol style="list-style-type: none"> <li>1. Dosage Forms: Updated to include new dosage form, 1.5 mg.</li> </ol>	<p>01.01.2023</p>
<p>RxA.711.Nexviazyme</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4: Updated to remove prior diagnostic criteria "Patient has measurable signs of Pompe disease, such as impairment in pulmonary function or motor weakness".</li> <li>2. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria Nexviazyme is not prescribed concurrently with Lumizyme®.</li> <li>3. Initial Approval Criteria, I.A.6: Updated to remove prior criteria pertaining to indication Pompe disease "Member should NOT meet any of the following:             <ol style="list-style-type: none"> <li>a. Concomitant use of alglucosidase alfa (Lumizyme®);</li> <li>b. Previous failure of alglucosidase alfa (Lumizyme®);</li> <li>c. Patient is not able to ambulate 40 meters without stopping and without an assistive device;</li> <li>d. Patient has Pompe-specific cardiac hypertrophy;</li> <li>e. Patient requires invasive ventilation;</li> <li>f. Patient has a percent-predicted FVC of &lt;30% or ≥ 85%".</li> </ol> </li> <li>4. Initial Approval Criteria, I.A.6: Updated dosing criteria from Requested dose must meet one of the following (a or b):</li> </ol>	<p>01.01.2023</p>

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	<ul style="list-style-type: none"> <li>a. If the patient weighs <math>\geq 30</math> kg: 20 mg/kg;</li> <li>b. If the patient weighs <math>&lt;30</math> kg: 40 mg/kg to Requested dose must meet one of the following (a or b): <ul style="list-style-type: none"> <li>a. If the patient weighs <math>\geq 30</math> kg: 20 mg/kg every 2 weeks;</li> <li>b. If the patient weighs <math>&lt;30</math> kg: 40 mg/kg every 2 weeks.</li> </ul> </li> <li>5. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Nexviazyme is not prescribed concurrently with Lumizyme®</li> <li>6. Continued Therapy Approval Criteria, II.A.4: Updated dosing criteria from Requested dose must meet one of the following (a or b): <ul style="list-style-type: none"> <li>a. If the patient weighs <math>\geq 30</math> kg: 20 mg/kg;</li> <li>b. If the patient weighs <math>&lt;30</math> kg: 40 mg/kg to Requested dose must meet one of the following (a or b): <ul style="list-style-type: none"> <li>a. If the patient weighs <math>\geq 30</math> kg: 20 mg/kg every 2 weeks;</li> <li>b. If the patient weighs <math>&lt;30</math> kg: 40 mg/kg every 2 weeks.</li> </ul> </li> </ul> </li> <li>7. Continued Therapy Approval Criteria, II.A: Updated approval duration criteria from 6 months to 12 months.</li> <li>8. Appendix D, General Information: Updated to include new information regarding Pompe disease manifests as a clinical spectrum that varies with respect to age at onset*, rate of disease progression, and extent of organ involvement. Patients can present with a variety of signs and symptoms, which can include cardiomegaly, cardiomyopathy, hypotonia, muscle weakness, respiratory distress (eventually requiring assisted ventilation), and skeletal muscle dysfunction. *Although infantile-onset disease typically presents in the first year of life, age of onset alone does not necessarily distinguish between infantile-and late-onset disease since juvenile-onset disease can present prior to 12 months of age.</li> </ul>	
<p>RxA.712.Opzelura</p>	<ul style="list-style-type: none"> <li>1. Background: Updated to include new indication "Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older".</li> <li>2. Background: Updated to include limitation(s) of use, " Use in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended ".</li> <li>3. Dosing Information, Nonsegmental vitiligo: Updated to include new indication nonsegmental vitiligo.</li> <li>4. Dosing Information, Dosing Regimen, Opzelura™: Updated to include dosing information for indication Nonsegmental vitiligo.</li> </ul>	<p>01.01.2023</p>

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	<ol style="list-style-type: none"> <li>5. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria “Opzelura™ is not prescribed concurrently with biologic disease-modifying antirheumatic drugs (e.g., Humira, Enbrel, Taltz, Stelara), JAK inhibitors (e.g., Xeljanz, Rinvoq, Olumiant), or potent immunosuppressants (e.g., azathioprine, cyclosporine)”.</li> <li>6. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Nonsegmental vitiligo.</li> <li>7. Continued Therapy Approval Criteria, II.B: Updated to include approval criteria for indication, Nonsegmental vitiligo.</li> <li>8. Appendix B, Maximum Dose, clioquinol and hydrocortisone (Ala-Quin®): Updated maximum dose information from 60 grams per week to 2 to 4 times daily for indication Atopic dermatitis.</li> <li>9. Appendix B, Drug Name: Updated to include therapeutic alternatives: <ol style="list-style-type: none"> <li>a. betamethasone dipropionate/propylene glycol 0.05 % (Diprolene®);</li> <li>b. clobetasol propionate 0.05 % (Temovate®);</li> <li>c. diflorasone diacetate 0.05% topical cream, ointment;</li> <li>d. desoximetasone 0.05% (Topicort®)</li> <li>e. fluocinolone acetonide 0.025% (Synalar®)</li> <li>f. fluocinonide acetonide 0.05%</li> <li>g. triamcinolone acetonide 0.5% (Kenalog®) cream, ointment.</li> <li>h. mometasone 0.1% cream, ointment, lotion.</li> <li>i. alclometasone 0.05% cream, ointment,</li> <li>j. desonide 0.05% (Desowen®) cream, ointment, lotion</li> <li>k. hydrocortisone 2.5% cream, ointment</li> <li>l. tacrolimus (Protopic®), pimecrolimus (Elidel®)</li> <li>m. Eucrisa®</li> </ol> </li> </ol>	
<p>RxA.713.Qulipta</p>	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.2: Updated to remove prescriber criteria.</li> <li>2. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria Member does not have chronic migraine, defined as &gt; 15 headaches days/month with ≥ 8 migraine days/month for at least 3 months.</li> <li>3. Initial Approval Criteria, I.A.8: Updated to include new combination therapy criteria Qulipta™ is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Ubrelyv™, Vypti™).</li> <li>4. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Qulipta™ is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®,</li> </ol>	<p>01.01.2023</p>

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	<p>Ubrelyv™, Vyepti™).</p> <p>5. Appendix B, Maximum Dose, metoprolol (Lopressor®): Updated maximum dose information from 400 mg/day to 450 mg/day.</p>	
RxA.714.Trudhesa	1. Initial Approval Criteria I.A.5: Updated to remove Reyvow.	01.01.2023
RxA.715.Welireg	1. Initial Approval Criteria I.A.4: Updated to remove criteria patient must have ECOG performance status of 0 or 1.	01.01.2023
RxA.716.Brexafemme	1. Initial Approval Criteria I.A.2: Updated to add infectious disease physician.	01.01.2023
RxA.717.Nurtec.ODT	<p>1. Initial Approval Criteria, I.A.3: “Member must experience (a or b): a. at least 4 headaches per month or; b. at least 8 headache days per month;” was replaced with Member does not have chronic migraine, defined as ≥15 headache days/month with ≥ 8 migraine days/month for at least 3 months;</p> <p>2. Initial Approval Criteria, I.A.4: Updated to include new dosing criteria Member experiences ≥ 4 migraine days per month for at least 3 months.</p> <p>3. Initial Approval Criteria, I.A.8: Updated to include new combination therapy criteria Nurtec® ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Qulipta™, Ubrelyv®, Vyepti™);</p> <p>4. Initial Approval Criteria: I.B.3: Updated to remove Member experiences between 4 and 14 headache days per month.</p> <p>5. Initial Approval Criteria I.B.5: Updated to remove Member must currently be treated with one of the following preventative treatments, unless previously ineffective, contraindicated, or clinically significant adverse effects are experienced (a, b, or c): a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate); b. beta-blockers (e.g., metoprolol, propranolol, timolol); c. antidepressants (e.g., amitriptyline, venlafaxine);</p> <p>6. Initial Approval Criteria, I.B.7: Updated to include new combination therapy criteria Nurtec® ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Qulipta™, Ubrelyv®, Vyepti™).</p> <p>7. Continued Therapy Approval Criteria II.A.3: Updated to include new combination therapy Nurtec® ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Qulipta™, Ubrelyv®, Vyepti™);</p>	01.01.2023

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	<ol style="list-style-type: none"> <li>8. Continued Therapy Approval Criteria II.B.3: updated to include new combination therapy Nurtec® ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Qulipta™, Ubrovelvy®, Vyepti™);</li> <li>9. Appendix B, Maximum Dose, metoprolol (Lopressor®): Updated maximum dose information from 400 mg/day to 450 mg/day.</li> <li>10. Appendix B, Drug Name: Updated to include new therapeutic alternative             <ol style="list-style-type: none"> <li>a. frovatriptan (Frova®)</li> <li>b. sumatriptan (Imitrex® nasal spray)</li> <li>c. sumatriptan (Imitrex®)</li> <li>d. rizatriptan (Maxalt® /Maxalt MLT®)</li> <li>e. eletriptan (Relpax®)</li> <li>f. zolmitriptan (Zomig®/Zomig ZMT)</li> </ol> </li> <li>11. Appendix B, Drug Name: Updated to include generic therapeutic alternative             <ol style="list-style-type: none"> <li>a. naratriptan</li> <li>b. almotriptan</li> </ol> </li> <li>12. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative Qulipta™.</li> </ol>	
<p>RxA.718.Reyvow</p>	<ol style="list-style-type: none"> <li>1. Dosage Forms: Updated to remove discontinued dosage form, 200 mg.</li> <li>2. Initial Approval Criteria I.A.3: Updated to add Trial and failure of Nurtec and Ubrovelvy, unless contraindicated, or clinically significant adverse effects are experienced;</li> <li>3. Initial Approval Criteria I.A.4: Updated to remove criteria that member must experience 4-14 headache days per month.</li> <li>4. Appendix B, Drug Name: Updated to include therapeutic alternatives             <ol style="list-style-type: none"> <li>a. naratriptan</li> <li>b. almotriptan</li> <li>c. frovatriptan (Frova®)</li> <li>d. eletriptan (Relpax®)</li> </ol> </li> </ol>	<p>01.01.2023</p>
<p>RxA.728.Skyrizi</p>	<ol style="list-style-type: none"> <li>1. Background: Updated to include new indication Moderately to severely active Crohn's disease in adults.</li> <li>2. Dosing Information, Indication: Updated to include new indication Crohn's disease.</li> <li>3. Dosing Information, Dosing Regimen, Skyrizi®: Updated to include dosing information for indication Crohn's disease.</li> <li>4. Dosing Information, Maximum Dose, Skyrizi®: Updated to include maximum dosing information for indication Crohn's.</li> <li>5. Dosage Forms: Updated to include new dosage form:             <ol style="list-style-type: none"> <li>a. Single-dose prefilled cartridge: 360 mg/2.4 mL (150 mg/mL);</li> </ol> </li> </ol>	<p>01.01.2023</p>

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	<ul style="list-style-type: none"> <li>b. Single-dose vial: 600 mg/10 mL (60 mg/mL).</li> <li>6. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of Plaque Psoriasis (PsO) to Diagnosis of moderate to severe Plaque Psoriasis (PsO) as evidenced by involvement of one of the following (a, b, or c):             <ul style="list-style-type: none"> <li>a. Body surface area ≥ 3%;</li> <li>b. Hands, feet, scalp, face, or genital area;</li> </ul> </li> <li>7. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Crohn's disease.</li> <li>8. Continued Therapy Approval Criteria, II.A.3.b: Updated to include new maximum dose criteria 360 mg/dose subcutaneously every 8 weeks for Crohn's disease.</li> <li>9. Appendix B, Dosing Regimen, methotrexate, Humira®, Cimzia®, Stellara®: Updated to include dosing information for indication Crohn's disease.</li> <li>10. Appendix B, Maximum Dose, methotrexate, Humira®, Cimzia®, Stellara®: Updated to include maximum dose information for indication Crohn's disease.</li> <li>11. Appendix B, Drug Name: Updated to include therapeutic alternatives:             <ul style="list-style-type: none"> <li>a. azathioprine (Azasan®, Imuran®);</li> <li>b. Tysabri®.</li> </ul> </li> <li>12. Appendix D, Warnings and Precautions: Updated to include new warning and precaution Hepatotoxicity in Treatment of Crohn's Disease: Drug-induced liver injury during induction has been reported. Monitor liver enzymes and bilirubin levels at baseline and, during induction, up to at least 12 weeks of treatment. Monitor thereafter according to routine patient management.</li> </ul>	
<p>RxA.730.Actemra</p>	<ul style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5: Updated to remove exception trial and failure criteria "Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.</li> <li>2. Initial Approval Criteria, I.A.5 and I.C.5: Updated trial and failure criteria to include drug Enbrel®.</li> </ul>	<p>01.01.2023</p>
<p>RxA.733.Cosentyx</p>	<ul style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel® and Xeljanz®/ XR.</li> <li>2. Initial Approval Criteria, I.A.5.b: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Xeljanz®/XR or Taltz® unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced.</li> <li>3. Initial Approval Criteria, I.B.5.a and I.C.4.a: Updated to remove exception trial and failure criteria "Exception: If</li> </ul>	<p>01.01.2023</p>

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	<p>a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.”</p> <p>4. Initial Approval Criteria, I.B.5.a and I.C.4.a: Updated trial and failure criteria to include drug Enbrel®.</p>	
RxA.734.Breyanzi		01.01.2023
RxA.734.Enbrel	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5.a: Updated to remove prior trial and failure criteria "Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/Simponi Aria®, or Xeljanz®/XR unless contraindicated or clinically significant adverse effects are experienced. Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required".</li> <li>2. Initial Approval Criteria, I.A.5.b: Updated to remove prior trial and failure criteria "Trial and failure of both Actemra® and Orencia® unless contraindicated or clinically significant adverse effects are experienced".</li> <li>3. Initial Approval Criteria, I.B.4.a: Updated to remove prior trial and failure criteria "Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/Simponi Aria®, Skyrizi®, Stelara®, Tremfya® or Xeljanz®/XR unless contraindicated or clinically significant adverse effects are experienced. Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.”</li> <li>4. Initial Approval Criteria, I.B.4.b: Updated to remove prior trial and failure criteria "Trial and failure of both Taltz® and Orencia® unless contraindicated or clinically significant adverse effects are experienced".</li> <li>5. Initial Approval Criteria, I.C.5: Updated to remove prior trial and failure criteria "Trial and failure of all of the following agents unless contraindicated or clinically significant adverse effects are experienced for all: Humira®, Actemra®, Orencia®, Xeljanz®".</li> <li>6. Initial Approval Criteria, I.D.5.a: Updated to remove prior trial and failure criteria "Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Simponi®/Simponi Aria®, unless contraindicated or clinically significant adverse effects are experienced. Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.”</li> <li>7. Initial Approval Criteria, I.D.5.b: Updated to remove</li> </ol>	01.01.2023

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	<p>prior trial and failure criteria "Trial and failure of at least one (1) of the following agents: Taltz® or Xeljanz®/XR unless contraindicated or clinically significant adverse effects are experienced".</p> <p>8. Initial Approval Criteria, I.E.5.a: Updated to remove prior trial and failure criteria "Trial and failure of at least three (3) of the following agents: Humira®, Cimzia®, Skyrizi®, Stelara® or Tremfya® unless contraindicated or clinically significant adverse effects are experienced. Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required."</p> <p>9. Initial Approval Criteria, I.E.5.b: Updated to remove prior trial and failure criteria "Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced".</p>	
RxA.736.Ilumya	<p>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®.</p> <p>2. Initial Approval Criteria, I.A.5.a: Updated to remove exception trial and failure criteria "Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required".</p>	01.01.2023
RxA.738.Kevzara	<p>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®.</p> <p>2. Initial Approval Criteria, I.A.5: Updated to remove exception trial and failure criteria "*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required."</p>	01.01.2023
RxA.739.Kineret	<p>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel® and Simponi Aria®.</p> <p>2. Initial Approval Criteria, I.A.5.a: Updated to remove exception about trial and failure criteria "*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required."</p>	01.01.2023
RxA.740.Olumiant	<p>1. Background: Updated to include new indication:</p> <ul style="list-style-type: none"> <li>a. the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.</li> <li>b. the treatment of adult patients with severe alopecia areata.</li> </ul>	01.01.2023

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	<ol style="list-style-type: none"> <li>2. Background: Updated to include limitation(s) of use: Olumiant® is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.</li> <li>3. Dosing Information, Dosing Regimen, Olumiant®: Updated to include dosing information for indication:             <ol style="list-style-type: none"> <li>a. COVID-19</li> <li>b. Alopecia areata</li> </ol> </li> <li>4. Dosage Forms: Updated to include new dosage form, 4 mg Tablets.</li> <li>5. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®.</li> <li>6. Approval Criteria, I.A.5.a: Updated to remove exception about trial and failure criteria "*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required."</li> <li>7. Initial Approval Criteria, I.A.6: Updated to include new documentation criteria             <ol style="list-style-type: none"> <li>a. Clinical disease activity index (CDAI) score (see Appendix D).</li> <li>b. Routine assessment of patient index data 3 (RAPID3) score (see Appendix D).</li> </ol> </li> <li>8. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Coronavirus-19 Infection.</li> <li>9. Initial Approval Criteria, I.C.: Updated to include approval criteria for indication, Alopecia Areata.</li> <li>10. Continued Therapy Approval Criteria II.B: Updated to include approval criteria for indication, Coronavirus-19 Infection.</li> <li>11. Continued Therapy Approval Criteria II.C: Updated to include approval criteria for indication, Alopecia Areata.</li> <li>12. Appendix D, General Information: Updated to include new information regarding:             <ol style="list-style-type: none"> <li>a. CDAI</li> <li>b. RAPID3</li> </ol> </li> </ol>	
RxA.741.Orencia	<ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5: Updated trial and failure criteria to include drug Enbrel®.</li> <li>2. Initial Approval Criteria, I.A.5 and I.C.5: Updated to remove exception about trial and failure criteria "*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required."</li> </ol>	01.01.2023

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	<p>3. Initial Approval Criteria, I.B.4: Updated trial and failure criteria from Trial and failure of at least two (2) first line agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Stelara®, Stelara®, Skyrizi®, Tremfya® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required to Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Enbrel®, Rinvoq®, Simponi®/ Simponi Aria®, Stelara®, Skyrizi®, Tremfya® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced.</p>	
RxA.745.Rinvoq	<p>1. Initial Approval Criteria, I.D.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 one (1) of the following agents: Humira®, Simponi®, unless contraindicated or clinically significant adverse effects are experienced.</p> <p>2. Initial Approval Criteria, I.E.5: Updated trial and failure criteria from Trial and failure of at least two (2) of the following: Humira®, Cimzia®, Simponi®/Simponi Aria®, unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira, Cimzia®, Simponi®/ Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required to 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.</p>	01.01.2023
RxA.746.Siliq	<p>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®.</p>	01.01.2023
RxA.747.Stelara	<p>1. Background: Updated to remove detail(s) pertaining to indication active psoriatic arthritis (PsA), "alone or in combination with methotrexate".</p> <p>2. Background: Updated to include new information regarding age, "Pediatric patients 6 years and older with Active psoriatic arthritis (PsA)".</p> <p>3. Dosing Information, Dosing Regimen, ustekinumab (Stelara®): Updated dosing information from Weight based dosing subcutaneously at weeks 0 and 4, followed by maintenance dose every 12 weeks Adult:Weight ≤ 100 kg: 45 mg (some patients may</p>	01.01.2023

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	<p>require doses of 90 mg or maintenance dosing of every 8 weeks), Weight &gt; 100 kg: 90 mg (some patients may require maintenance dosing of every 8 weeks) to Weight based dosing subcutaneously at weeks 0 and 4, followed by maintenance dose every 12 weeks          Adult: Weight ≤ 100 kg: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks, Weight &gt; 100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks for indication PsO.</p> <ol style="list-style-type: none"> <li>4. Dosing Information, Dosing Regimen, ustekinumab (Stelara®): Updated dosing information for ages limits from Pediatrics (Age 6 years and older) to Pediatrics (Age 6- 17 years and older) for indication PsO.</li> <li>5. Dosing Information, Maximum Dose, ustekinumab (Stelara®): Updated maximum dosing information from 90 mg every 8 weeks to 90 mg every 12 weeks for indication PsO.</li> <li>6. Dosing Information, Maximum Dose, ustekinumab (Stelara®): Updated to include maximum dosing information for indication PsA with co-existent PsO.</li> <li>7. Dosing Information, Dosing Regimen, ustekinumab (Stelara®): Updated to include dosing information for ages Pediatrics (Age 6- 17 years and older) for indication PsA.</li> <li>8. Dosing Information, Maximum Dose, ustekinumab (Stelara®): Updated maximum dosing information from 90 mg every 8 weeks to 90 mg every 12 weeks for indication PsA.</li> <li>9. Initial Approval Criteria, I.C.3: Updated age criteria from Age ≥ 18 years to Age ≥ 6 years.</li> <li>10. Initial Approval Criteria, I.C.4: Updated dosing criteria from Dose does not exceed 45 mg every 12 weeks to If request is for a dose increase, new dose does not exceed one of the following: (a or b)             <ol style="list-style-type: none"> <li>a. PsA: 45 mg every 12 weeks;</li> <li>b. PsA with co-existent PsO and weighing &gt;100 kg: 90 mg every 12 weeks.</li> </ol> </li> <li>11. Continued Therapy Approval Criteria, II.A.3. from If request is for a dose increase, new dose does not exceed one of the following: (a or b);             <ol style="list-style-type: none"> <li>a. For UC, CD: 90 mg every 8 weeks;</li> <li>b. For PsA: 45 mg every 12 weeks. to If request is for a dose increase, new dose does not exceed one of the following: (a, b, c or d);                 <ol style="list-style-type: none"> <li>a. For UC, CD: 90 mg every 8 weeks;</li> <li>b. For PsA: 45 mg every 12 weeks.</li> <li>c. For PsO: 90 mg every 12 weeks;</li> <li>d. For PsO with co-existent: 90 mg every 12 weeks.</li> </ol> </li> </ol> </li> </ol>	
RxA.748.Taltz	1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®, Rinvoq® and	01.01.2023

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	<p>Xeljanz®/XR®.</p> <p>2. Initial Approval Criteria, I.B.5 and I.C.4: Updated trial and failure criteria to include drug Enbrel®.</p>	
RxA.749.Xeljanz_Xeljanz XR	<p>1. Initial Approval Criteria, 1.C.6: Updated trial and failure criteria from Trial and failure of at least two (2) of the following agents: Humira®, Simponi®/ Simponi Aria®, Cimzia®, unless contraindicated or clinically significant adverse effects are experienced; Exception: If a total of two TNF inhibitors (Humira, Cimzia®, Simponi®/ Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required to 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.</p> <p>2. Initial Approval Criteria, 1.D.6: 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 one (1) of the following agents: Humira®, Simponi®, unless contraindicated or clinically significant adverse effects are experienced.</p> <p>3. Initial Approval Criteria, I.E.6: Updated trial and failure criteria to include drug Enbrel®.</p>	01.01.2023
RxA.774.Breyanzi	<p>1. Background: Updated to include new information regarding use of Breyanzi:</p> <ol style="list-style-type: none"> <li>"refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy."</li> <li>"refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age."</li> </ol> <p>2. Dosing Information, Indication: Updated from LBCL to LBCL after two or more lines of therapy.</p> <p>3. Dosing Information, Dosing Regimen, Breyanzi®: Updated to include dosing information for indication LBCL after one line of therapy.</p> <p>4. Initial Approval Criteria, 1.A.4: Updated to include new request criteria:</p> <ol style="list-style-type: none"> <li>Disease is refractory or member has relapsed after ≥ 2 lines of systemic therapy that includes an anti-CD20 therapy (e.g., rituximab) and one anthracycline containing regimen (e.g., doxorubicin);</li> </ol>	01.01.2023

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	<ul style="list-style-type: none"> <li>b. Disease that is refractory (defined as no complete remission) to or has relapsed (defined as complete remission followed by biopsy-proven disease relapse) no more than 12 months after first-line chemoimmunotherapy that included an antiCD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin);</li> <li>c. Member is not eligible for HSCT due to comorbidities or age (see Appendix D for examples) and disease is refractory (defined as no complete remission) to or has relapsed (defined as complete remission followed by biopsy-proven disease relapse) after first-line chemoimmunotherapy that included an anti-CD20 monoclonal antibody (e.g., rituximab*) and anthracycline-containing regimen (e.g., doxorubicin);</li> </ul> <p>5. Initial Approval Criteria, 1.A.5: Updated to include new diagnostic criteria Member does not have primary CNS disease.</p> <p>6. Initial Approval Criteria, 1.A.6: Updated to include new prior treatment criteria Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Abecma®, Carvykti™, Kymriah™, Tecartus™, Yescarta™).</p> <p>7. Initial Approval Criteria, 1.A.7: Updated to include new combination therapy criteria Breyanzi is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Abecma, Carvykti, Kymriah, Tecartus, Yescarta).</p> <p>8. Appendix B, Drug Name: Updated to include therapeutic alternatives:</p> <ul style="list-style-type: none"> <li>a. First-Line Treatment Regimens: <ul style="list-style-type: none"> <li>• RCHOP (Rituxan®, cyclophosphamide, doxorubicin, vincristine, prednisone)</li> <li>• RCEPP (Rituxan®, cyclophosphamide, etoposide, prednisone, procarbazine)</li> <li>• RCDOP (Rituxan®, cyclophosphamide, liposomal doxorubicin, vincristine, prednisone)</li> <li>• DA-EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicine) + Rituxan®</li> <li>• RCEOP (Rituxan®, cyclophosphamide, etoposide, vincristine, prednisone)</li> <li>• RGCVP (Rituxan®, gemcitabine, cyclophosphamide, vincristine, prednisone)</li> </ul> </li> <li>b. Second-Line Treatment Regimens: bendamustine (Bendeka®) ± Rituxan® <ul style="list-style-type: none"> <li>• CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± Rituxan®</li> </ul> </li> </ul>	
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	<ul style="list-style-type: none"> <li>• CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± Rituxan®</li> <li>• DA-EPOCH ± Rituxan®</li> <li>• GDP (gemcitabine, dexamethasone, cisplatin) ± Rituxan®</li> <li>• gemcitabine, dexamethasone, carboplatin ± Rituxan®</li> <li>• GemOx (gemcitabine, oxaliplatin) ± Rituxan®</li> <li>• gemcitabine, vinorelbine ± Rituxan®</li> <li>• lenalidomide ± Rituxan®</li> <li>• Rituxan®</li> <li>• DHAP (dexamethasone, cisplatin, cytarabine) ± Rituxan®</li> <li>• DHAX (dexamethasone, cytarabine, oxaliplatin) ± Rituxan®</li> <li>• ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin) ± Rituxan®</li> <li>• ICE (ifosfamide, carboplatin, etoposide) ± Rituxan®</li> <li>• MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± Rituxan®</li> </ul> <p>9. Appendix D, General Information: Updated to include new information regarding PILOT study evaluated transplant-ineligible patients with relapsed or refractory LBCL after one line of chemoimmunotherapy</p>	
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**New Step Therapy**

N/A

**Updated Step Therapy**

Drug Name; Strength(s); & Dosage Form(s)	Step Edit Details	Effective Date
N/A	N/A	N/A

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