2 Quarter 2023 Drug Formulary and Clinical Updates

Date of Notice: 06/01/2023

Formulary Updates

Drug Name, Strength(s), & Dosage Form(s)	Description of Change	Formulary Status	Alternative Drug(s) (if applicable)	Effective Date
Pepaxto 20 mg intravenous solution	Formulary Deletion; PA Deletion	Non- Formulary	Velcade, Blenrep	07.01.2023
Benzamycin 3%-5% topical gel	Formulary Deletion; ST Deletion	Non- Formulary	Retin-A, Onexton, Twyneo, Amzeeq, Winlevi	07.01.2023
Acanya 1.2 - 2.5% topical gel with pump	Formulary Deletion; ST Deletion	Non- Formulary	Retin-A, Onexton, Twyneo, Amzeeq, Winlevi	07.01.2023
Benzaclin 1-5 % topical gel; Benzaclin pump 1%-5 % topical gel	Formulary Deletion; ST Deletion	Non- Formulary	Retin-A, Onexton, Twyneo, Amzeeq, Winlevi	07.01.2023
Ziana 1.2-0.025 % topical gel	Formulary Deletion; ST Deletion	Non- Formulary	Retin-A, Onexton, Twyneo, Amzeeq, Winlevi	07.01.2023
Veltin 1.2%-0.025 % topical gel	Formulary Deletion; ST Deletion	Non- Formulary	Retin-A, Onexton, Twyneo, Amzeeq, Winlevi	07.01.2023
Epiduo 0.1%-2.5 % topical gel with pump	Formulary Deletion	Non- Formulary	Retin-A, Onexton, Twyneo, Amzeeq, Winlevi	07.01.2023
Rezlidhia 150 mg capsule	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Krazati 200 mg tablet	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Sunlenca 300 mg tablet	Formulary Addition; PA Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Sunlenca 309 mg/mL subcutaneous solution	Formulary Addition; PA Addition; Specialty Addition; SPS	Non-Preferred brand		07.01.2023

	Addition; Day Supply Addition			
Briumvi 25 mg/mL intravenous solution	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Orserdu 86 mg tablet; Orserdu 345 mg tablet	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Preferred brand		07.01.2023
Jaypirca 50 mg tablet; Jaypirca 100 mg tablet	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Amjevita Autoinjector 40 mg/0.8 mL subcutaneous auto-injector	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Preferred brand		07.01.2023
Filspari 200 mg tablet; Filspari 400 mg tablet	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Altuviiio 500 (+/-) unit intravenous solution; Altuviiio 250 (+/-) unit intravenous solution; Altuviiio 1,000 (+/-) unit intravenous solution; Altuviiio 2,000 (+/-) unit intravenous solution; Altuviiio 4,000 (+/-) unit intravenous solution; Altuviiio 3,000 (+/-) unit intravenous solution	Formulary Addition; PA Addition; Specialty Addition	Non-Preferred brand		07.01.2023
Skyclarys 50 mg capsules	Formulary Addition; QL Addition; Specialty Addition	Preferred brand		07.01.2023
Azstarys 39.2 mg-7.8 mg capsule; Azstarys 26.1 mg-5.2 mg capsule; Azstarys 52.3 mg-10.4 mg capsule	Formulary Addition	Non-Preferred brand		07.01.2023
Jornay PM 20 mg capsule, delayed release,extended release sprinkle; Jornay PM 40 mg capsule, delayed release, extended release sprinkle; Jornay PM 80 mg capsule, delayed release, extended release sprinkle;	Formulary Addition	Non-Preferred brand		07.01.2023

Jornay PM 60 mg capsule, delayed release, extended release sprinkle; Jornay PM 100 mg capsule, delayed release, extended release sprinkle				
Sunosi 150 mg tablet; Sunosi 75 mg tablet	Formulary Addition; PA Addition	Preferred brand		07.01.2023
Mydayis 37.5 mg capsule extended release 24 hr; Mydayis 12.5 mg capsule extended release 24 hr; Mydayis 25 mg capsule extended release 24 hr; Mydayis 50 mg capsule extended release 24 hr	Formulary Addition	Non-Preferred brand		07.01.2023
Winlevi 1 % topical cream	Formulary Addition; PA Addition	Non-Preferred brand		07.01.2023
Onexton 1.2 % (1% base)-3.75% topical gel; Onexton 1.2 % (1% base)-3.75% topical gel with pump	ST Deletion	Non-Preferred brand		07.01.2023
Twyneo 0.1%- 3% topical cream	ST Deletion	Non-Preferred brand		07.01.2023

New Prior Authorization Policies

- RxA.786.Furoscix
- RxA.787.Kuvan
- RxA.788.Gleevec
- RxA.789.Rezlidhia
- RxA.790.Krazati
- RxA.791.Sunlenca
- RxA.792.Briumvi
- RxA.793.Orserdu
- RxA.794.Jaypirca
- RxA.795.Altuviiio
- RxA.796.Skyclarys
- RxA.797.Filspari
- RxA.798.Winlevi

Updated Prior Authorization Policies

Policy Name	Policy Changes	Effective Date
RxA.147.Gralise	1. Initial Approval Criteria I.A.4: Trial and failure of generic pregabalin immediate-release (at doses up to 450 mg/day) and controlled-release (at doses up to 660 mg/day) each used for ≥ 30-days, unless clinically significant adverse effects are experienced, or both are contraindicated. 2. Trial and failure of a ≥ 30-day trial of a tricyclic	07.01.2023

	antidepressant (TCA) (e.g., amitriptyline, nortriptyline, imipramine), unless clinically significant adverse effects are experienced, member's age is ≥ 65, or all are contraindicated. 3. Appendix B, Drug Name: Updated to include new therapeutic alternative pregabalin (Lyrica®). Appendix B: Therapeutic alternatives updated to add Pregabalin extended release (Lyrica CR®), amitriptyline (Elavil®), desipramine (Norpramin®), nortriptyline (Pamelor®).	
RxA.149.Galafold	1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of Fabry disease to Diagnosis of Fabry disease confirmed by one of the following (a or b): a. Enzyme assay demonstrating a deficiency of alpha-galactosidase activity; b. DNA testing. 2. Initial Approval Criteria, I.A.2: Updated prescriber criteria from Prescribed by or in consultation with a clinical geneticist, nephrologist or a physician who specializes in the treatment of Fabry disease to Prescribed by or in consultation with a clinical geneticist, cardiologist, nephrologist, neurologist, or a physician who specializes in the treatment of Fabry disease. 3. Policy updated to add Appendix F: Clinical manifestations of Fabry disease.	07.01.2023
RxA.150.Gattex	1. Initial Approval Criteria I.A.5: Updated to remove, a. For members 18 years of age or older: Use of parenteral nutrition/IV fluids occurs at least three (3) times a week; or b. For members under 18 years of age: Use of parenteral nutrition/IV fluids account for at least 30% of caloric and/or fluid/electrolyte needs. 2. Initial Approval Criteria I.A.5: Updated to remove Failure of a 4-week trial of somatropin (e.g., Zorbtive®) unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria I.A.4: Updated to add Weight ≥ 10 kg. 4. Appendix D: Updated to add information about risk of acceleration of neoplastic growth, intestinal malignancy and non gastrointestinal malignancy.	07.01.2023
RxA.151.Gilotrif	1. Appendix B, Drug Name: Updated to include new therapeutic alternative a. erlotinib (Tarceva®) b. Vizimpro® c. Iressa®	07.01.2023
RxA.158.Acthar Gel	1. Clinical Policy Title, Drug(s) Applied: Updated from H.P. Acthar® Gel to Acthar® Gel.	07.01.2023

	2. Background: Updated to remove indication a. Rheumatic Disorders b. Collagen Diseases c. Dermatologic Diseases d. Allergic States e. Ophthalmic Diseases f. Respiratory Diseases g. Edematous State 3. Initial Approval Criteria, I.A.4: Updated to include new diagnosis confirmation criteria Diagnosis is confirmed by electroencephalogram. 4. Initial Approval Criteria, I.C: Updated to remove approval criteria for Other FDA Approved Indications. 5. Continued Therapy Approval Criteria II.C: Updated to remove approval criteria for Other FDA Approved Indications. 6. Appendix B, Drug Name: Updated to include new therapeutic alternative. a. methylprednisolone (Medrol®, SoluMedrol®) b. prednisone (Deltasone®) c. dexamethasone (Decadron®) 7. Appendix B, Drug Name: Updated to remove therapeutic alternatives. a. tacrolimus (Prograf®) b. cyclosporine (Neoral®, Sandimmune®) c. cyclophosphamide d. mycophenolate (CellCept®) e. Rituxan® f. Glucocorticoid 8. Appendix D, General Information: Updated information regarding adverse events. 9. Appendix D, General Information: Updated to remove information regarding FDA Approved Indications Requiring Efficacy and Safety Documentation. 10. Appendix D, General Information: Updated to include information regarding Non FDA Approved Indications.	
RxA.163.Ibrance	1. Background: Updated to remove detail pertaining to indication Breast Cancer "in postmenopausal women or in men." 2. Initial Approval Criteria, I.A.6: Updated to include new criteria pertaining to indication Breast cancer, if member is a premenopausal female, member has been treated with ovarian ablation or is receiving ovarian suppression. 3. Initial Approval Criteria, I.A.8 and I.B.7: Updated to include new concurrent therapy criteria Ibrance® is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Verzenio®, Kisqali®). 4. Continued Therapy Approval Criteria, II.A.3: Updated to include new concurrent therapy criteria Ibrance® is not prescribed concurrently with another CDK 4/6 inhibitor	07.01.2023

	therapy (e.g., Verzenio®, Kisqali®). 5. Appendix D, General Information: Updated to include new information regarding if member is a premenopausal female treated with ovarian ablation or is receiving ovarian suppression.	
RxA.167.Inlyta	1. Initial Approval Criteria, I.A.2: Updated prescriber criteria from For clear cell histology, prescribed as (must meet one of the following): a. Subsequent single agent therapy (failure of previous therapy, see Appendix B); b. As first line therapy for favourable risk, poor/intermediate risk in combination therapy with pembrolizumab or avelumab; c. As subsequent therapy in combination with pembrolizumab; to Prescribed in one of the following ways (a or b): a. As a single agent therapy; b. For clear cell histology, in combination with Keytruda® or Bavencio®; 2. Initial Approval Criteria, I.A.3: Updated to remove prior criteria pertaining to indication Renal Cell Carcinoma. 3. Initial Approval Criteria, I.B.5: Updated to remove prior trial and failure criteria "Failure of lenvatinib (Lenvima®)* or sorafenib (Nexavar®)* unless contraindicated or clinically adverse effects are experienced; *Prior authorization may be required." 4. Initial Approval Criteria, I.B.5.a: Updated to remove prior dosing criteria "Dose does not exceed 20 mg daily". 5. Initial Approval Criteria, I.C: Updated to include approval criteria for off label indication Soft Tissue Sarcoma. 6. Initial Approval Criteria, I.A and I.B: Updated approval duration from 6 months to 12 months. 7. Continued Therapy Approval Criteria, II.A: Updated approval duration from 6 months to 12 months. 8. Appendix B, Drug Name: Updated to remove therapeutic alternatives: a. Votrient® b. sunitinib (Sutent®) c. Opdivo® ± Yervoy® d. bevacizumab (Avastin®) ± (Intron® A, erlotinib (Tarceva®) or everolimus (Afinitor®/Afinitor® Disperz)) e. Proleukin® f. Cabometyx® g. temsirolimus (Torisel®) h. everolimus (Afinitor®/Afinitor® Disperz) ± Lenvima® i. erlotinib (Tarceva®) j. lenvatinib (Lenvima® k. sorafenib (Nexavar®) 9. Appendix D, General Information: Updated to include new information regarding moderate hepatic impairment.	07.01.2023

RxA.169.Iclusig	1. Initial Approval Criteria, I.A.1: Updated indication from Diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia to Diagnosis of chronic myelogenous/myeloid leukemia (CML); 2. Initial Approval Criteria, I.A.4.a: Updated trial and failure criteria from Member has experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, Bosulif®, Sprycel®, Tasigna®) to Disease is in chronic phase and member has experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, Bosulif®, Sprycel®, Tasigna®); 3. Initial Approval Criteria, I.A.4.c: Updated to include new request criteria Request is for accelerated or blast phase CML for members whom no other TKI therapy is indicated. 4. Initial Approval Criteria, I.B.4.a: Updated trial and failure criteria from Member has experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, Bosulif®, Sprycel®, Tasigna®) to No other TKI therapy is indicated (e.g., imatinib, Bosulif®, Sprycel®, Tasigna®, Iclusig®); 5. Initial Approval Criteria, I.A, I.B and I.C: Updated approval duration criteria from 6 months to 12 months for Commercial. 6. Appendix B, Drug Name: Updated to include new therapeutic alternative a. imatinib (Gleevec®) b. Bosulif® c. Sprycel® d. Tasigna®	07.01.2023
RxA.170.Imbruvica	1. Background: Updated indication from adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy to adult and pediatric patients age 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy. 2. Dosing Information, Dosing Regimen, ibrutinib (Imbruvica®): Updated to include dosing information for indication cGVHD. 3. Dosing Information, Maximum Dose, ibrutinib (Imbruvica®): Updated to include maximum dosing information for indication cGVHD. 4. Dosing Information, Dosing Regimen, ibrutinib (Imbruvica®): Updated to include hepatic impairment dosing information for indication cGVHD. 5. Dosage Forms: Updated to include new dosage form, Oral suspension: 70 mg/mL. 6. Initial Approval Criteria, I.A.3: Updated age criteria from Member is ≥ 18 years of age to Age ≥ 1 year. 7. Initial Approval Criteria, I.A.5: "Member meets one of the following (a or b):	07.01.2023

	a. Failure of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; b. If there is a intolerance or contraindication to systemic corticosteroids, failure of an immunosuppressant [e.g., mycophenolate mofetil, calcineurin inhibitors (e.g., cyclosporine, tacrolimus), sirolimus] at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experience;" was replaced with Trial and failure of at least one other systemic therapy (e.g., systemic corticosteroids, immunosuppressants) unless contraindicated or clinically significant adverse effects are experienced. 8. Initial Approval Criteria, I.A.6: Updated to include new combination therapy criteria Imbruvica® is not prescribed concurrently with Jakafi® or Rezurock®. 9. Initial Approval Criteria, I.A, I.B, I.C, I.D. I.E and I.F: Updated approval duration criteria from 6 months to 12 months for Commercial. 10. Initial Approval Criteria, I.B.4.c.: Updated to remove prior combination therapy criteria "bendamustine and rituximab". 11. Initial Approval Criteria, I.B.4.d: Updated to remove prior combination therapy criteria "For histologic (Richter's) transformation of CLL/SLL to diffuse large B-cell lymphoma (DLBCL), Opdivo® (nivolumab) or Keytruda® (pembrolizumab)". 12. Initial Approval Criteria, I.C.4.a: Updated combination therapy criteria from Prescribed in combination with rituximab as pre-treatment for HyperCVAD to Prescribed in combination with rituximab as pre-treatment in order to limit the number of cycles of aggressive induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone). 13. Initial Approval Criteria, I.D.1: Updated diagnostic criteria from Diagnosis of MZL to Diagnosis of one of the following MZL subtypes (a, b, c, or d): a. Gastric MALT lymphoma; b. Nongastric MALT lymphoma (noncutaneous); c. Nodal MZL; d. Splenic MZL. 14. Initial Approval Criteria, I.F.1.a: "Non-Hodgkin's (B-cell) lymphoma or any of its subtypes (see Appendix D for NCCN-recommended subtypes)" was replaced with B-cell lymphoma subtype (i, ii, iii, iv, or v): i. AIDS-related non-germinal center DLBCL; ii. High-grade B-cell lymphoma; iii. Post-transplant lymphoproliferative disorder (PTLD); iv. DLBCL; v. Histologic transformation of CLL/SLL to DLBCL.	

	15. Initial Approval Criteria, I.F.5.b: "For CNS lymphoma or non-Hodgkin's (B-cell) lymphoma: Received at least one (1) prior therapy (see Appendix B), unless contraindicated or clinically significant adverse effects are experienced to all;" was replaced with "For primary CNS lymphoma, request is for use as either induction therapy or for relapsed or refractory disease." 16. Initial Approval Criteria, I.F.5.c: Updated to include new trial and failure criteria For B-cell lymphoma, received ≥ 1 prior line of systemic therapy (see Appendix B), unless contraindicated or clinically significant adverse effects are experienced to all. 17. Initial Approval Criteria, I.F.6.a: Updated to remove prior dosing criteria "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." 18. Continued Therapy Approval, II.A.3: Updated to include new combination therapy criteria For cGVHD, Imbruvica is not prescribed concurrently with Jakafi or Rezurock. 19. Appendix B, Drug name: Updated to include generic therapeutic alternative pentostatin. 20. Appendix B, Dosing Regimen: Updated to remove indication follicular lymphoma from below mentioned therapeutic alternatives: a. RCHOP [cyclophosphamide, doxorubicin (Adriamycin®), vincristine (Vincasar PFS®), prednisone]/RDHAP; b. Bendeka®, bendamustine (Treanda®) + rituximab (Rituxan®); c. (Revlimid® + rituximab (Rituxan®); d. rituximab (Rituxan®); e. RCVP [rituximab (Rituxan®), cyclophosphamide, doxorubicin (Adriamycin®), vincristine (Vincasar PFS®)]; f. Bendeka®, bendamustine (Treanda®) + Gazyva®; g. CHOP + Gazyva®. 21. Appendix B, Dosing Regimen, cyclosporine (Gengraf®, Neoral®, Sandimmune®): Updated dosing information from 3 to 5 mg/kg/day to Varies for indication cGVHD. 22. Appendix B, Dosing Regimen, tacrolimus (Prograf®): Updated dosing information from 1g/day orallyor 0.06 mg/kg orally twice daily to Varies for indication cGVHD. 23. Appendix B, Maximum Dose, tacrolimus (Prograf®): Updated dosing information from 1g/day to Varies for indication cGVHD. 24. Appendix B, Dosing Regimen, sirolimus (Rapamune®): Updated dosing information from 6 mg loading doseorally, then 2 mg orally once daily to Varies for indication cGVHD.	

	25. Appendix B, Maximum Dose, sirolimus (Rapamune®): Updated dosing information from Maintenance: 2 mg/day to Varies for indication cGVHD. 26. Appendix B, Dosing Regimen, systemic corticosteroids (e.g., prednisone, prednisolone, methylprednisolone): Updated dosing information from An equivalent dose of prednisone 1 mg/kg/day orally to Varies for indication cGVHD. 27. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. imatinib (Gleevec®); b. Jakafi® (ruxolitinib); c. Rezurock™ (belumosudil). 28. Appendix D, General Information: Updated to remove information regarding: a. Non-Hodgkin's (B-cell) lymphoma subtypes supported as NCCN category 2A recommended uses for ibrutinib; b. MCL; c. MZL.	
RxA.171.Increlex	1. Initial Approval Criteria, I.A.1.a, I.A.1.b & I.A.1.c: Updated to remove prior diagnosis evidence criteria " (i.e., inherited growth hormone insensitivity) and associated growth failure as evidenced by all of the following (a, b, and c): a. Basal IGF-1 standard deviations (SD) score is 3 at the baseline; b. Normal or elevated GH level; c. Height standard deviation score is ≤ 3.0 at baseline." 2. Initial Approval Criteria, I.A.5: Updated to include new lab values criteria IGF-1 serum level is ≥ 3 standard deviations (SD) below the mean. 3. Initial Approval Criteria, I.A.6: Updated to remove prior documentation criteria "Documentation of baseline height is provided at the time of request". 4. Initial Approval Criteria, I.A.6: Updated to include new lab values criteria GH serum level is normal or elevated. 5. Initial Approval Criteria, I.A.7: Updated to include new eligibility criteria Height is ≥ 3 SD below the mean for age and sex. 6. Initial Approval Criteria, I.A.8 and I.B.6: Updated to include new criteria pertaining to indication Severe Primary IGF-1 Deficiency and Growth Hormone Insensitivity, "Member does not have malignant neoplasia or a history of malignancy". 7. Initial Approval Criteria, II.A.4: Updated to include new criteria pertaining to indication Severe Primary IGF-1 Deficiency and Growth Hormone Insensitivity, "Member does not have malignant neoplasia or a history of malignancy". 8. Appendix D, General Information: Updated to remove information regarding Definitions:	07.01.2023

	○ Height standard deviation score less than or equal to –3.0 and; ○ Basal IGF-1 standard deviation score less than or equal to –3.0 and; ○ Normal or elevated growth hormone (GH). *GH production and secretion is normal or above normal; therefore, exogenous GH treatment would be ineffective.	
RxA.172.Ingrezza	No updates	07.01.2023
RxA.173.Inrebic	1. Initial Approval Criteria, I.A.6: Updated to include new trial and failure criteria Trial and failure of Jakafi®, unless contraindicated or clinically significant adverse effects are experienced. 2. Initial Approval Criteria, I.A. and I.B: Approval duration for commercial line of business updated from 6 months to 12 months. 3. Initial Approval Criteria, I.A.B.3: Updated to remove If treating for JAK2 rearrangement in blast phase criteria. 4. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative Jakafi®.	07.01.2023
RxA.175.Istodax	1. Initial Approval Criteria I.B.5: Updated from Request meets one of the following (a or b): a. Dose does not exceed 14 mg/m2 for three days of a 28-day cycle; b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off label use (prescriber must submit supporting evidence) to Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*Prescribed regimen must be FDA-approved or recommended by NCCN. 2. Appendix E: Updated to add, although the FDA-labelled indication for peripheral T-cell lymphoma was withdrawn in August 2021 following findings from the confirmatory phase 3 trial, the NCCN continues to support use in this indication based on the results of the phase 2 trial and other subsequent trials.	07.01.2023
RxA.176.Idhifa	1. Initial Approval Criteria I.A: Commercial approval duration updated from 6 months to 12 months. 2. Appendix B, Drug Name: Updated to include new generic therapeutic alternative: a. cytarabine with idarubicin or daunorubicin; b. cytarabine with idarubicin or daunorubicin or mitoxantrone.	07.01.2023
RxA.177.Exjade_Jadenu	No updates	07.01.2023
RxA.179.Kadcyla	1. Initial Approval Criteria, I.B.2: Updated to include new diagnostic criteria disease is recurrent, advanced, or metastatic. 2. Continued Therapy Criteria, II.A: Commercial approval	07.01.2023

	duration updated to 12 months to 6 months.	
RxA.181.Kisqali_Kisqali.Femara	1. Initial Approval Criteria, I.A.6: Updated to include new prescribing criteria "If request is for Kisqali® Femara®, prescribed as initial endocrine based therapy." 2. Initial Approval Criteria, I.A.7: Updated to include new contraindication/adverse event criteria the requested agent is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Verzenio®, Ibrance®); 3. Continued Therapy Approval Criteria, II.A.4: Updated to include new contraindication/adverse event criteria the requested agent is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Verzenio®, Ibrance®); 4. Initial Approval Criteria, I.A.8: Updated to include gender based criteria If member is a premenopausal female, member has been treated with ovarian ablation or is receiving ovarian suppression (see Appendix D); 5. Appendix D, General Information: Updated to include information regarding Ovarian ablation.	07.01.2023
RxA.183.Kymriah	1. Background: Updated to include new indication adult patients with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). 2. Dosing Information, Indication: Updated to include new indication Follicular lymphoma. 3. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Follicular Lymphoma. 4. Initial Approval Criteria I.A.8, I.B.8, I.C.6: Updated to add Kymriah is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Abecma, Breyanzi, Tecartus, Yescarta).	07.01.2023
RxA.184.Sancuso_Sustol	1. Background: Updated indication from Granisetron is a serotonin (5-HT3) receptor antagonist that is indicated for prevention of chemotherapy-associated nausea and vomiting. In addition, granisetron tablet is indicated for prophylaxis of radiation therapy-associated emesis to Granisetron is a serotonin (5-HT3) receptor antagonist that is indicated for prevention of chemotherapy-associated nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin. In addition, granisetron tablet is indicated for prophylaxis of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.	07.01.2023

	2. Initial approval Criteria I.C: Updated to be removed as it was off-label indication and granisetron IV injection to not require prior authorization. 3. Initial approval criteria I.A.5 and I.B.5: Updated from formulary 5-HT_3 to trial and failure of 5-$HT_{3\ e.g.,}$ ondansetron. 4. Dosage Forms, granisetron hydrochloride intravenous: Updated dosage form from 4mg/4mL to 0.1 mg/mL. 5. Appendix B, Drug Name: Updated to remove generic therapeutic alternative dolasetron. 6. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative: a. Aloxi®; b. Zofran®.	
RxA.186.Kanuma	1. Initial Approval Criteria and Continued Therapy Criteria: Updated to add Documentation of member's current weight (in kg).	07.01.2023
RxA.190.Kalydeco	1. Initial Approval Criteria, I.A: Updated to include new diagnostic criteria Diagnosis of CF to Diagnosis of CF confirmed by all of the following (a, b, c, and d):; a. Clinical symptoms consistent with CF in at least one organ system, or positive new born screen or genetic testing for siblings of patients with CF; b. Evidence of CFTR dysfunction confirmed by one of the following (i or ii) (see Appendix D): i. Elevated sweat chloride ≥ 60 mmol/L; ii. Genetic testing confirming the presence of two disease-causing mutations in CFTR gene, one from each parental allele; c. Presence of one mutation in the CFTR gene responsive to ivacaftor based on clinical and/or in vitro assay data (see Appendix E); d. Confirmation that a homozygous F508del mutation in the CFTR gene is not present. 2. Initial Approval Criteria I.A and Continued Therapy Criteria I.B: Updated to add Kalydeco is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Symdeko®, Trikafta™). 3. Appendix E, Information regarding CFTR Gene Mutations that are Responsive to Kalydeco® has been updated.	07.01.2023
RxA.192.Keytruda	1. Background: Updated to include new information regarding adjuvant treatment for indication Non-small cell lung cancer (NSCLC), "As a single agent, for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC". 2. Background: Updated indication for Adult: Additional Dosing Regimen of 400 mg Every 6 Weeks for Adult Classical Hodgkin Lymphoma and Adult Primary Mediastinal Large B-Cell Lymphoma.	07.01.2023

	3. Initial Approval Criteria, I.M.5.d: Updated to include new requesting criteria: As a single agent adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC. 4. Initial Approval Criteria, I.M.6: Updated to include new contraindication criteria: Member does not have contraindications to PD-1/PD-L1 inhibitor therapy (e.g., Opdivo®, Yervoy, Tecentriq®, Imfinzi®). 5. Initial Approval Criteria, I.S: Updated to remove approval criteria for Malignant Pleural Mesothelioma (off-label). 6. Appendix D, General Information: Updated to include new information regarding contraindications for treatment with PD-1/PD-L1 inhibitors.	
RxA.193.Bethkis_Kitabis.Pak_TOBI_TOBI.Podhaler	1. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with a pulmonologist, an infection disease specialist, or an expert in treatment of cystic fibrosis. 2. Initial Approval Criteria: Updated commercial approval duration from 6 months to 12 months.	07.01.2023
RxA.194.Korlym	1. Initial Approval Criteria I.A: Updated the commercial approval duration from 6 months to 12 months.	07.01.2023
RxA.198.Lenvima	1. Background: Updated indication from In combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma (EC) that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation to In combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H) ,who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. 2. Initial Approval Criteria, I.A, I.B, I.C, I.D, I.E and I.F: Updated Approval Duration from 6 months to 12 months for Commercial. 3. Initial Approval Criteria, I.C.4: Updated combination therapy criteria from Member meets one of the following (a or b); a. Will be used in combination with Keytruda®; b. Will be used in combination with Afinitor® and member meets one of the following (i or ii); i. If RCC histology is clear cell or unknown, failure of a prior antiangiogenic therapy (e.g Inlyta®, Sutent®, Votrient®, or Cabometyx®) unless contraindicated or clinically adverse effects are experienced;. ii. If RCC histology is non- clear cell, used as systemic therapy;	07.01.2023

	to Prescribed in one of the following (a or b); a. In combination with Keytruda®; b. In combination with Afinitor® and: i. If RCC histology is clear cell or unknown, failure of a prior antiangiogenic therapy (e.g Inlyta®, Sutent®, Votrient®, or Cabometyx®) unless contraindicated or clinically adverse effects are experienced. 4. Initial Approval Criteria, I.D.1: Updated indication from Diagnosis of unresectable hepatocellular carcinoma to Diagnosis of hepatocellular carcinoma. 5. Initial Approval Criteria, I.D.4.: Updated to remove prior disease progression criteria "Member must meet one of the following (a, b, or c): a. Have unresectable disease and are not a transplant candidate; b. Have liver-confined disease, inoperable by performance status, comorbidity or with minimal or uncertain extrahepatic disease; c. Have metastatic disease or extensive liver tumor burde." 6. Initial Approval Criteria, I.D.5: Updated to remove prior criteria pertaining to indication Hepatocellular Carcinoma, "Prescribed as single agent therapy". 7. Initial Approval Criteria, I.E.5: Updated diagnostic criteria from Disease is not MSI-H or dMMR (i.e., disease is not indicative of MMR gene mutation or loss of expression) to Disease is not MSI-H or pMMR. 8. Initial Approval Criteria, I.F.2: Updated to remove prior prescribing criteria " Used as single agent for one of the following (a, b, or c): a. Prescribed as first line therapy for members who cannot tolerate combination regimens for any of the following: i. Unresectable locally advanced disease in combination with radiation therapy; ii. Potentially resectable locally advanced disease; iii. Potentially resectable solitary metastasis or ipsilateral pleural metastasis; iv. Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis; v. Extrathoracic metastatic disease. b. Prescribed for postoperative treatment for members who are unable to tolerate first-line combination regimens after R1 or R2 resection; c. Prescribed as second-line therapy for one of the following: i. Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or	

	ipsilateral pleural metastasis; ii. Extrathoracic metastatic disease. 9. Initial Approval Criteria, I.F.4: Updated to include new criteria pertaining to indication Thymic Carcinomas, Prescribed as single agent therapy for members who have not tolerated or responded to NCCN recommended agents (see Appendix B); 10. Appendix B, Drug Name: Updated to include generic therapeutic alternative sorafenib tosylate. 11. Appendix B, Drug Name: Updated to include therapeutic alternatives: RCC therapeutic agents: • Avastin® (bevacizumab) • Cabometyx® (cabozantinib) • Keytruda® (pembrolizumab) • Inlyta® (axitinib) • Nexavar® (sorafenib) • Opdivo® (nivolumab) • Proleukin® (aldesleukin, rIL-2) • Sutent® (sunitinib) • Tarceva® (erlotinib) • Torisel® (temsirolimus) • Votrient® (pazopanib) • Yervoy® (ipilimumab) • Caprelsa® (vandetanib) • Cometriq® (cabozantinib) • carboplatin/paclitaxel • vandetanib (Caprelsa®); • Cometriq® • carboplatin/paclitaxel, • cisplatin/docetaxel, • cisplatin/doxorubicin, • carboplatin/paclitaxel/bevacizumab, • carboplatin/paclitaxel/trastuzumab, • ifosfamide/paclitaxel, • cisplatin/ifosfamide, • everolimus/letrozole, • Torisel® • Keytruda® 12. Appendix B, Drug Name: Updated to remove therapeutic alternatives: • Keytruda®, (Avastin®) , Cabometyx® ,®, Inlyta®, • sorafenib tosylate (Nexavar®), Opdivo®, • Proleukin® ,sunitinib®, sunitinib (Sutent®), • erlotinib (Tarceva®) ,), temsirolimus (Torisel®), Votrient®, Yervoy® • vandetanib (Caprelsa®) • Cometriq®	

RxA.199. Leukine	1. Initial Approval Criteria I.A.4, I.B.3, I.C.3, I.D.2: Updated to remove trial and failure of Neupogen®. 2. Initial Approval Criteria, I.A.5, I.B.4, I.C.4 and I.D.3: Updated to include new prescribing criteria Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle; 3. Continued Therapy Approval, I.A.3: Updated to include new prescribing criteria Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle; 4. Appendix B, Drug Name: Updated to include therapeutic alternatives Zarxio®.	07.01.2023
RxA.202.Lemtrada	1. Appendix B, Drug Name: Updated to include generic therapeutic alternative fingolimod hcl. 2. Appendix D, Warnings and Precautions: Updated to include new warning and precaution Autoimmune Encephalitis.	07.01.2023
RxA.203.Letairis	1. Appendix B, Drug Name: Updated to remove discontinued brand therapeutic alternative Adalat CC®.	07.01.2023
RxA.208.Mircera	1. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative Retacrit®.	07.01.2023
RxA.209.Ribavirin	1. Dosing Information, Dosing Regimen, ribavirin tablet and capsule: Updated dosing information to include weight based dosing information for paediatric patients for chronic hepatitis C.	07.01.2023
RxA.213.Mavenclad	1. Initial Approval Criteria, I.A.6: Updated to include new documentation criteria Documentation of baseline number of relapses per year and expanded disability status scale score. 2. Appendix D, General Information: Updated to include new information regarding vaccination of patients who are seropositive to varicella zoster virus.	07.01.2023
RxA.214.Mavyret	1. Continued Therapy Approval, II.A.3: Updated to include new prior treatment criteria Member is not treatment-experienced with both NS3/4A protease inhibitor AND NS5A inhibitors, such as combination therapies including Technivie™, Viekira, and Zepatier®.	07.01.2023
RxA.215.Mayzent	1. Dosage Forms: Updated to include new dosage form, Tablet 1 mg. 2. Initial Approval Criteria, I.A.1.a: Updated diagnostic criteria from Clinically isolated syndrome to Clinically isolated syndrome, and member is contraindicated to both or has experienced significant adverse effects to one of the following at up to maximally indicated doses: an interferon-beta agent (Avonex®, Betaseron®/Extavia®, Rebif®, or Plegridy®), glatiramer (Copaxone®, Glatopa®). 3. Initial Approval Criteria, I.A.1.b: Updated diagnostic criteria from Relapsing-remitting MS to Relapsing-remitting MS, and Trial and failure of all of the following at up to	07.01.2023

	maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, iii, and iv):* i. dimethyl fumarate (Tecfidera®); ii. Aubagio®; iii. Gilenya®; iv. An interferon-beta agent (Avonex®, Betaseron®/Extavia®, Rebif®, or Plegridy®) or glatiramer (Copaxone®, Glatopa®); 4. Initial Approval Criteria, 1.A.6: Updated to include new documentation criteria Documentation of baseline number of relapses per year and expanded disability status scale (EDSS) score. 5. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. Copaxone® b. Aubagio® c. Rebif® d. Betaseron®, Extavia® e. fingolimod (Gilenya®) f. dimethyl fumarate (Tecfidera®)	
RxA.217.Mepsevii	No updates	07.01.2023
RxA.221.Mozobil	No updates	07.01.2023
RxA.225.Marinol_Syndros	1. Initial Approval Criteria I.A.3: Updated to remove maximally indicated doses. 2. Appendix B, Dosing Regimen, Akynzeo® Capsule: Updated to remove "or 1 vial intravenously given 30 min prior to initiation of chemotherapy on day 1." 3. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. Anzemet® b. lorazepam (Ativan®)	07.01.2023
RxA.226.Mektovi	1. Initial Approval Criteria, I.A.2: Separated from I.A.1 to form a separate criteria. 2. Initial Approval Criteria, I.A.2.c: Updated Adjuvant therapy criteria from in combination with encorafenib, following complete resection of distant metastatic disease or in patients with unacceptable toxicities with dabrafenib/trametinib to Member has unacceptable toxicities to dabrafenib /trametinib or on the basis of agent side-effect profiles. 3. Initial Approval Criteria, I.A.2.d: Updated to include new disease criteria Member has limited resectable disease and meets all of the following (i and ii): i. Used as initial treatment in combination with encorafenib;	07.01.2023

	ii. Member has unacceptable toxicities to dabrafenib/trametinib or on the basis of agent side effect profiles and one of the following (1 or 2): 1) Member has stage III disease with clinical satellite/in-transit metastases; 2) Member has local satellite/in-transit recurrence 4. Initial Approval Criteria, I.B: Updated to include approval criteria for Off label indication Histiocytic Neoplasms.	
RxA.227.Mestinon	1. Dosing Information, Dosing Regimen, pyridostigmine oral solution (Mestinon®): Updated from 60-1,500 mg/day (average 600 mg/day) orally divided into 5 to 6 doses, spaced to provide maximum relief to 600 mg/day orally in divided doses spaced to provide maximum relief when maximum strength is needed. Adjust the dosage to the needs of the individual patient; dosage range, 60 to 1,500 mg/day. 2. Appendix B, Dosing Regimen, pyridostigmine tablet (Mestinon®): Updated dosing information from 60-1,500 mg/day (average 600 mg/day) orally divided into 5 to 6 doses, spaced to provide maximum relief to 600 mg/day orally in divided doses spaced to provide maximum relief when maximum strength is needed. Adjust the dosage to the needs of the individual patient; dosage range, 60 to 1,500 mg/day.	07.01.2023
RxA.229.Mulpleta	1. Initial Approval Criteria, I.A.6: Updated to include new concurrent therapy criteria Mulpleta® is not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet®, Nplate®, Promacta®).	07.01.2023
RxA.230.Myalept	No updates	07.01.2023
RxA.232.Mytesi	1. Appendix B, Dosing Regimen, loperamide (Imodium® A-D): Updated dosing information from 2 mg orally after each loose stool to 4 mg orally initially, followed by 2 mg orally after each loose stool. 2. Appendix B, Dosing Regimen, diphenoxylate/atropine (Lomotil®): Updated dosing criteria from once daily to 4 times daily until control achieved.	07.01.2023
RxA.233.Naglazyme	No updates	07.01.2023
RxA.235.Jatenzo_ Testim_ Vogelxo_ Natesto_ Testopel_ Xyosted	1. Dosing Information, Dosing Regimen, testosterone (Testopel®): Updated to include dosing information for indication Dosages in delayed puberty. 2. Dosing Information, Dosing Regimen, testosterone (Natesto®): Updated dosing information from 11 mg (2 pump actuations; 1 actuation per nostril) administered intranasally three times daily to 11 mg (2 pump actuations; 1 actuation per nostril) administered intranasally three times daily for a total daily dose of 33 mg for indication Hypogonadism (Primary and Hypogonadotropic).	07.01.2023

	3. Appendix B, Dosing Regimen, testosterone enanthate injection: Updated to include dosing information for indication Males with delayed puberty.	
RxA.237.Nexavar	1. Initial Approval Criteria, I.A.5 and I.C.5: Updated dosing criteria from dose does not exceed 800 mg/day to Request meets one of the following (a or b):* a. Dose does not exceed 800 mg/day. 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. 2. Initial Approval Criteria, I.D.5: Updated to remove prior criteria pertaining to indication Acute Myeloid Leukemia "Request is to be used as a component of repeating the initial successful induction regimen if late relapse (≥ 12 months since induction regimen) if not administered continuously and not stopped due to development of clinical resistance." 3. Initial Approval Criteria, I.D.5.b: Updated to include new prescribing criteria, As a single agent for maintenance therapy for member in remission postallogeneic stem cell transplantation. 4. Initial Approval Criteria, I.I.1.b: Updated to remove "primary treatment or treatment of gross residual disease (R2 resection) in abdominal wall tumors if time to response is more critical as a single agent (preferred) for (meets one of the following i, ii, or iii): i. Ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid; ii. Documented progression in anatomic location where progression would be morbid; iii. No documented progression in anatomic location where progression would be morbid if concerns for morbidity or significant symptoms;" 5. Appendix B, sunitinib malate: Updated to include generic therapeutic alternative sunitinib malate. 6. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. Qinlock® b. Sprycel®	07.01.2023
RxA.238.Nityr_Orfadin	1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Member has a clinical diagnosis of HT-1 confirmed by biochemical testing (e.g., detection of succinylacetone in the urine or blood), enzyme assay, or genetic testing to Diagnosis of HT-1 confirmed by one of the following (a or b):	07.01.2023

	a. Biochemical testing confirms elevated levels of succinylacetone in the urine or blood; b. Genetic testing confirms a mutation of the FAH gene;	
RxA.240.Nuedexta	1. Appendix D: Updated to add information about CNS-LS , self-administered questionnaire.	07.01.2023
RxA.242.Namenda XR Namzaric	1. Appendix B: Updated to add Aricept ODT® and Aricept ODT® as therapeutic alternatives.	07.01.2023
RxA.244.Natpara	1. Appendix B, Dosing Regimen, calcium carbonate (Caltrate®, Tums®): Updated dosing information from 1-3 gm by mouth once daily in divided doses to Oral: 500 mg to 4 g/day as calcium carbonate (equivalent to 200 mg to 1.6 g of elemental calcium) in 1 to 3 divided doses for indication hypocalcemia. 2. Appendix B, Dosing Regimen, calcium citrate: Updated dosing information from 1-3 gm by mouth once daily in divided doses to Oral: 200 mg to 1 gm/day (as elemental calcium) as a single dose or in divided doses for indication hypocalcemia. 3. Appendix B, Maximum Dose, calcium carbonate (Caltrate®, Tums®): Updated maximum dose information from 3 gm/day to 4 gm/day for indication hypocalcemia. 4. Appendix B, Maximum Dose, calcium citrate: Updated maximum dose information from 3 gm/day to 1 gm/day for indication hypocalcemia.	07.01.2023
RxA.245.Nerlynx	1. Initial Approval Criteria I.B.4: Updated from Prescribed in combination with capecitabine for recurrent, advanced, or metastatic disease, and member has received two or more prior anti-HER2 based regimens used in the metastatic setting to be Prescribed in combination with capecitabine; 2. Appendix B, Drug Name: Updated to include brand-name therapeutic alternatives Perjeta®, Kadcyla® and Enhertu®.	07.01.2023
RxA.246.Ocaliva	1. Background: Updated to include new information regarding accelerated approval, this indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. 2. Appendix B, Drug Name: Update brand name from Urso® to Urso 250®. 3. Appendix C, Boxed Warnings: Updated to include Ocaliva® is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.	07.01.2023
RxA.247.Palynziq	1. Initial Approval Criteria, I.A.5: Updated to include new criteria pertaining to indication Phenylketonuria, Member is currently on a phenylalanine-restricted diet and will	07.01.2023

	continue this diet during treatment with Palynziq®. 2. Continued Therapy Approval, II.A.2: Updated to include new criteria pertaining to indication Phenylketonuria, Member is currently on a phenylalanine-restricted diet and will continue this diet during treatment with Palynziq®. 3. Continued Therapy Approval, II.A.3.a: Updated to remove prior lab criteria "Blood Phe level has decreased by ≥ 20% from pre-treatment baseline." 4. Continued Therapy Approval, II.A.3.c: The member has not responded to Palynziq® at a dose of 20 mg/day for 24 weeks followed by 40 mg/day for 16 weeks, but a dose titration to 60 mg per day is being requested after failure to meet therapeutic targets (a or b above) [only the 60 mg per day dose will be approved] was replaced with (b or c): a. Request is for 40 mg per day and member has previously used 20 mg per day continuously for at least 6 months without achieving blood Phe control; b. Request is for 60 mg per day and member meets both of the following (i and ii): i. Member has previously used 40 mg per day continuously for at least 16 weeks without achieving blood Phe control; ii. Member has not used 60 mg per day continuously for more than 16 weeks without achieving blood Phe control;	
RxA.248.Pegasys_PegIntron	1. Initial Approval Criteria, 1.B.3.a: Updated diagnostic criteria from Two elevated ALT lab values within the past 12 months (e.g., 70 IU/L or greater for men, 50 IU/L or greater for women) and HBV DNA levels 20,000 IU/ml or greater to Two elevated ALT lab values within the past 12 months (e.g., 70 IU/L or greater for men, 50 IU/L or greater for women) and HBV DNA levels 20,000 IU/ml or greater; in HBeAg positive members or > 2,000 IU/mL in HBeAg negative members; 2. Initial Approval Criteria, 1.B.3.b: Updated diagnostic criteria from Diagnosis of cirrhosis and member is ≥ 18 years of age to Diagnosis of cirrhosis, HBV DNA level > 2,000 IU/mL, and age ≥ 18 years. 3. Initial Approval Criteria off label indications I.C, I.D, I.E, I.F and I.G are merged into one as I.C “NCCN-Recommended Off-Label Indications (off-label)”.	07.01.2023
RxA.249.Perjeta	1. Initial Approval Criteria, I.B, I.C and I.D merged to I.D as “Additional NCCN Recommended Uses (off-label)” for indication colon cancer, head neck and rectal cancers to make criteria more simplified; 2. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Central Nervous System Cancers. 3. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Hepatobiliary Cancers.	07.01.2023

	4. Appendix B, Drug Name: Updated to include new therapeutic alternatives: a. Kadcyla® b. (lapatinib) Tykerb® c. Nerlynx®	
RxA.250.Piqray	1. Initial Approval Criteria I.A.1: Updated from Diagnosis of recurrent or stage IV HR-positive, HER2-negative, PIK3CA mutation positive breast cancer to diagnosis of breast cancer. 2. Initial Approval Criteria I.A.7.a and Continued therapy criteria II.A.4.a: Updated to remove two tablets requirement. 3. Appendix D, General Information: Updated to include new information regarding warning and precautions.	07.01.2023
RxA.251.Polivy	1. Initial Approval Criteria, I.B.1.a: Updated to remove prior diagnostic criteria "High grade B- cell lymphoma". 2. Initial Approval Criteria, I.B.4: Updated to remove prior criteria pertaining to indication HGBL or AIDS-related B-cell lymphoma, "For HGBL or AIDS-related B-cell lymphoma, member is not a candidate for allogeneic or autologous stem cell transplant". 3. Initial Approval Criteria, I.B.4: Updated to include new criteria pertaining to indication Follicular lymphoma, For requests other than FL grade 1-2, member is not a candidate for allogeneic or autologous stem cell transplant. 4. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. FL (grade 1-2) i. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab; ii. CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab; b. Post-Transplant Lymphoproliferative Disorder i. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab; ii. CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab; c. HIV- related B-Cell Lymphoma i. R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin; ii. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab; d. Histologic Transformation of Nodal Marginal Zone Lymphoma to DLBCL i. RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone). 5. Appendix B, Drug name: Updated to remove generic	07.01.2023

	therapeutic alternative CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± rituximab. 6. Appendix D, General Information: Updated to include new information regarding DLBCL subtypes.	
RxA.252.Poteligeo	1. Initial Approval Criteria I.B.5: Updated to remove Used as second line or subsequent therapy in patients with acute or lymphoma subtypes which did not respond to first-line therapy. 2. Appendix D, Warnings and Precautions: Updated to include new warning and precaution to add autoimmune complications (glomerulonephritis).	07.01.2023
RxA.254.Qualaquin	1. Initial Approval Criteria I.B.2: Updated to add requirement for use in combination with clindamycin per IDSA and CDC.	07.01.2023
RxA.258.Orenitram Remodulin Tyvaso	No updates	07.01.2023
RxA.260.Radicava_Radicava_ORS	1. Drug applied, Background, Dosing Information, Dosage Forms, Clinical Policy was updated to include information related to new drug Radicava ORS®. 2. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria independent living status (defined as patients who can eat a meal, excrete, or move with oneself alone, and do not need assistance in everyday life). 3. Initial Approval Criteria, I.A.9.a: Updated to include new dosing criteria, One of the following (i or ii): i. For intravenous administration: 60 mg per day for each treatment cycle; ii. For oral administration: 105 mg per day for each treatment cycle. 4. Continued Therapy Approval Criteria, II.A.3.a: Updated to include independent living status; 5. Continued Therapy Approval Criteria, II.A.4.a: Updated to include new dosing criteria, One of the following (i or ii): i. For IV administration: 60 mg per day for each treatment cycle; ii. For oral administration: 105 mg per day for each treatment cycle.	07.01.2023
RxA.261.Ravicti	1. Initial Approval Criteria, I.1.a, I.1.b, I.1.c, I.1.d and I.1.e: Updated to remove prior diagnostic criteria "caused by one or more of the following, confirmed by enzymatic, biochemical or genetic analysis: a. Carbamyl phosphate synthetase I (CPSI) deficiency; b. Ornithine transcarbamylase (OTC) deficiency; c. Argininosuccinate synthetase (ASS) deficiency (also known as classic citrullinemia or type I citrullinemia, CTLN1); d. Argininosuccinate lyase (ASL) deficiency (also known as argininosuccinic aciduria); e. Arginase deficiency." 2. Initial Approval Criteria, I.A.4: Updated trial and failure	07.01.2023

	criteria from For members with UCD caused by CPSI, OTC, or ASS deficiency Inadequate response to sodium phenylbutyrate, unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of sodium phenylbutyrate, unless contraindicated or clinically significant adverse effects are experienced. 3. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Medication is prescribed in conjugation with a protein-restricted diet.	
RxA.263.Reclast	1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Request is for one of the following indications (a, b, or c): a. Osteoporosis; b. Prevention of osteoporosis; c. Paget's disease of bone; to Request is for one of the following indications (a, b, or c): a. Treatment and prevention of PMO or GIO; b. Treatment of male osteoporosis; c. Treatment of Paget's disease of bone. 2. Initial Approval Criteria, I.A.3: Updated to remove prior lab values criteria "Member should have creatinine clearance ≥ 35 mL/min, in not more than last 3 days at the time of request." 3. Initial Approval Criteria, I.A.4: Updated to remove requesting criteria "For osteoporosis-related indications" as the criteria applies to both the indications Osteoporosis and Paget's Disease of Bone. 4. Continued Therapy Approval, II.A.4: Updated to remove prior lab values criteria "Member should have creatinine clearance ≥ 35 mL/min, in not more than last 3 days at the time of request." 5. Appendix B, Dosing Regimen and maximum dose, alendronate: Updated to include dosing information for indication Treatment of Paget's disease. 6. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative Fosamax®. 7. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative etidronate disodium. 8. Appendix D, General Information: Updated to remove information regarding hormonal therapy for prostate cancer. 9. Appendix D, General Information: Updated to include new information regarding diagnostic biochemical evaluation of Paget's disease.	07.01.2023
RxA.264.Repatha	1. Initial Approval Criteria, I.A.1.a.i.b).f: Updated diagnosis criteria from Medications which can increase lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives to Medications that have had a	07.01.2023

	clinically relevant contributory effect on the current degree of the member's elevated lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives. 2. Initial Approval Criteria, I.A.1.b.ii: Updated to include new diagnostic criteria, stress test using treadmill. 3. Initial Approval Criteria, I.A.4.b: Updated age criteria from for all other hyperlipidemias age: ≥ 18 years to for all other primary hyperlipidemias a (not including HeFH) or ASCVD ag ≥ 18 years. 4. Initial Approval Criteria, I.A.7.b: Updated to include new attestation criteria Provider attestation that member requires > 25% additional lowering of LDL-C. 5. Initial Approval Criteria, I.A and I.B: Updated from 6 months to 3 months for Commercial and Medicaid. 6. Initial Approval Criteria, I.B.3.a and I.B.3.b: Updated duration of therapy in criteria from within the last 30 days to within the last 60 days. 7. Initial Approval Criteria, I.B.3.b.ii: Updated to include new criteria pertaining to indication HoFH, ≥ 55 mg/dL if member has ASCVD and is at very high risk (see Appendix I). 8. Initial Approval Criteria, I.B.4: Updated to include new combination therapy criteria for members ≥ 18 years old and on statin therapy, both of the following (a and b): a. Repatha is prescribed in conjunction with a statin at the maximally tolerated dose; b. Member has been adherent for at least the last 4 months to maximally tolerated doses of one of the following statin regimens (I, ii, or iii): i. A high intensity statin (see Appendix E); ii. A moderate intensity statin (see Appendix E) and member has one of the following (a or b): a) Intolerance to two high intensity statins; b) A statin risk factor (see Appendix G); iii. A low intensity statin and member has one of the following (a or b): a) Intolerance to one high and one moderate intensity statins; b) A statin risk factor (see Appendix G) and history of intolerance to two moderate intensity statins. 9. Initial Approval Criteria, I.B.5: Updated combination therapy criteria from If member ≤ 10 years old , member has been adherent to a high intensity statin (see Appendix E) regimen for at least the last four (4) months, unless one of the following applies (a, b, or c): a. Statin therapy is contraindicated per Appendix F;	

	b. Member has been adherent to a moderate intensity statin (see Appendix E) regimen for at least the last four (4) months due to one of the following (i or ii): i. Intolerance to two (2) high intensity statins; ii. A statin risk factor (see Appendix G); and history of intolerance to two (2) moderate intensity statins; c. Member is unable to take a high or moderate intensity statin due to one of the following (i or ii): i. Intolerance to two (2) high and two (2) moderate intensity statins; ii. A statin risk factor (see Appendix G) and history of intolerance to two (2) moderate intensity statins to For member ≥ 18 years old and on statin therapy, both of the following (a or b): a. Statin therapy is contraindicated per Appendix F; b. For member who are statin intolerant, member has tried at least two (2) statins, , one of which must be hydrophilic (pravastatin, fluvastatin, or rosuvastatin), and member meets one of the following (i or ii): i. Member has documented statin risk factor (see Appendix G); ii. Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b): a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge; b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly). 10. Initial Approval Criteria, I.B.6: Updated combination therapy criteria from If member ≤ 10 years old, member has been adherent to ezetimibe therapy for at least the last four (4) months, unless contraindicated per Appendix F or a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection) to If age ≥ 18 years, one of the following (a or b): a. Member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last four (4) months, unless contraindicated per Appendix F or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);	

	b. Provider attestation that member requires > 25% additional lowering of LDL-C. 11. Continued Therapy Approval Criteria, II.A.4.b.i: Updated dosing criteria from 420 mg every 2 weeks to 420 mg per month for indication HoFH. 12. APPENDIX I, Updated to include new Appendix I: Criteria for Defining Patients at Very High Risk of Future ASCVD Events.	
RxA.267.Rhofade	1. Initial Approval Criteria I.A.4:Updated to add ivermectin cream as an option for failure. 2. Appendix B, Drug Name: Updated to include new therapeutic alternative ivermectin cream 1% (Soolantra®).	07.01.2023
RxA.270.Rozlytrek	1. Background Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive was replaced with Adult patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 2. Initial Approval Criteria, I.A.5: Updated diagnostic criteria from Disease is ROS1 positive to Disease is ROS1 positive as detected by an FDA-approved test. 3. Appendix D: Updated to remove cervical cancer, angiosarcoma and solitary fibrous tumor as no longer recommended by NCCN.	07.01.2023
RxA.271.Rydapt	1. Initial Approval Criteria I.A.6: Updated to add post induction therapy. 2. Appendix D, General Information: Updated to include new information regarding warning and precaution.	07.01.2023
RxA.272.Ragwitek	1. Appendix B, Dosing Regimen, OTC fexofenadine (Allegra Allergy®): Updated dosing information from 6-months to 2 years: 15 mg orally once daily to ≥ 6-months to < 2 years: <10.5 kg: Oral: 15 mg every 12 hours and ≥10.5 kg: Oral: 30 mg every 12 hours for indication allergic rhinitis.	07.01.2023
RxA.277.Jynarque Samsca	1. Dosage Forms, tolvaptan (Jynarque®): Updated dosage form (7-day and 28-day blister-packs): 45 mg with 15 mg, 60 mg with 30 mg, 90 mg with 30 mg to 15 mg, 30 mg, 45 mg, 60 mg and 90 mg.	07.01.2023
RxA.278.Sandostatin Sandostatin LAR Depot	No updates	07.01.2023
RxA.281.Siklos	No updates	07.01.2023
RxA.283.Somavert	1. Initial Approval Criteria, I.A.1: Updated to include new diagnostic criteria a. Pre-treatment IGF-I level above the upper limit of normal based on age and gender for the reporting laboratory; b. Serum growth hormone (GH) level ≥ 1 µg/mL after a 2-hour oral glucose tolerance test;) 2. Appendix B, Drug Name: Updated to include generic therapeutic alternative lanreotide acetate, pasireotide pamoate.	07.01.2023

RxA.284.Sporanox Tolsura	1. Dosage Forms: Updated dosage form from Itraconazole (Sporanox®): Capsules 100 mg, Oral solution 10 mg/ml to Itraconazole (Sporanox®): Capsules 100 mg, Oral solution 10 mg/ml (150 ml). 2. Initial Approval Criteria I.E.3: Updated from for Tolsura® requests, failure of generic itraconazole capsules unless contraindicated or clinically significant adverse effects are experienced (e.g., contraindications to the excipients) to Trial and failure of generic itraconazole capsules, unless contraindicated or clinically significant adverse effects are experienced. 3. Appendix B, Maximum Dose, voriconazole (Vfend®): Updated maximum dose information from Weight ≥ 40 kg: 800 mg per day, Weight < 40 kg: 400 mg per day to Weight ≥ 40 kg: 600 mg per day Weight < 40 kg: 300 mg per day for indication aspergillosis. 4. Appendix C, Contraindications: Updated to include new contraindication Coadministration with venetoclax is contraindicated in patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) during the dose initiation and ramp-up phase of venetoclax. 5. Appendix C, Contraindications: Updated to remove contraindication Onmel™: levacetylmethadol (levomethadyl)	07.01.2023
RxA.290.Uptravi	No updates	07.01.2023
RxA.302.Flolan_Veletri	1. Appendix B, Maximum Dose, Procardia XL®: Updated maximum dose information from 120 mg/day to Procardia XL®: 240 mg/day for indication PAH. 2. Appendix B, Maximum Dose, Dilt-XR® & Tiazac®, Taztia XT®, Cardizem® LA, Matzim® LA: Updated maximum dose information from 540 mg/day to 720 mg/day for indication PAH. 3. Appendix B, Maximum Dose, Cardizem® CD & Cartia XT®: Updated maximum dose information from 480 mg/day to 540 mg/day for indication PAH. 4. Appendix B, Maximum Dose, amlodipine (Norvasc®): Updated maximum dose information from Adult: 10 mg/day, Pediatric: 5 mg/day to Adult: 30 mg/day, Pediatric: 10 mg/day for PAH.	07.01.2023
RxA.305.Xermelo	1. Initial Approval Criteria I.A.2:Updated to remove maximally indicated doses. 2. Appendix C, Contraindications: Updated to include new contraindication History of hypersensitivity to telotristat. 3. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.	07.01.2023
RxA.317.Xospata	1. Initial Approval Criteria, I.A.5.b: Updated dosing criteria to remove “Dose is supported by practice guidelines or peer-	07.01.2023

	reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)." 2. Initial Approval Criteria, I.B.5.a: Updated dosing criteria to remove "Dose does not exceed 120 mg (3 tablets) per day." 3. Continued Therapy Approval Criteria II.A.3.b: Updated dosing criteria to remove "Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)." 4. Continued Therapy Approval Criteria II.B.3.a: Updated dosing criteria to remove "Dose does not exceed 120 mg (3 tablets) per day."	
RxA.318.Xtandi	1. Initial Approval Criteria I.A.5: Updated to remove as secondary hormone therapy * for M0 castration-resistant disease and PSA doubling time (PSADT) ≤ 10 months. 2. Initial Approval Therapy I.A.6: Updated to remove as secondary hormone therapy * for castration-resistant distant metastatic (M1) disease, and if received no prior docetaxel and no prior novel hormone therapy. 3. Initial and Continued therapy Criteria: Verbiage indicating number of capsules (e.g. 2 capsules per day) removed from dose does not exceed criteria.	07.01.2023
RxA.320.Xeloda	1. Background: Updated to remove prior information regarding Adjuvant Colon Cancer, Metastatic Colorectal Cancer and Metastatic Breast Cancer • Adjuvant colon cancer (i.e., patients with Dukes' C colon cancer) • Metastatic Colorectal Cancer ○ First-line as monotherapy when treatment with fluoropyrimidine therapy alone is preferred. • Metastatic Breast Cancer ○ In combination with docetaxel after failure of prior anthracycline containing therapy ○ As monotherapy in patients resistant to both paclitaxel and an anthracycline-containing regimen." 2. Background: Updated to include new information regarding Colorectal Cancer, Breast Cancer, Gastric, Esophageal, or Gastroesophageal Junction Cancer and Pancreatic Cancer. 3. Dosing Information, Indication, Dosing Regimen and Maximum dose: Updated to include new dosing information for indications, Breast Cancer, Colorectal Cancer, Pancreatic Cancer and Gastric, Esophageal or Gastroesophageal Junction Cancer. 4. Initial Approval Criteria, I.A.1: Updated diagnostic criteria to include "advanced or metastatic". 5. Initial Approval Criteria, I.A.4: Updated to include new prescribing criteria: a. As single agent if an anthracycline- or taxane-containing chemotherapy is not indicated;	07.01.2023

	b. In combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy. 6. Initial Approval Criteria, I.A.6.b: Updated to include new dosing criteria, Dose does not exceed 1250 mg/m2 twice a day on days 1 to 14, every 21 days in combination with docetaxel 75 mg/m2 on day 1 of each cycle. 7. Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of colorectal or rectal cancer to Diagnosis of colorectal cancer and any one of the following (a, b or c): a. Stage III colon cancer; b. Locally advanced rectal cancer; c. Unresectable or metastatic colorectal cancer. 8. Initial Approval Criteria, I.B.4.e: Updated to include new prescribing criteria As a single agent or as a component of a combination chemotherapy regimen. 9. Initial Approval Criteria, I.B.6: Updated dosing criteria to: a. Adjuvant Treatment of Colon Cancer (maximum of 8 cycles) and Unresectable or Metastatic Colorecta Cancer (i or ii): i. Single agent: Dose does not exceed 1250 mg/m2 twice a day on days 1 to 14, every 21 day; ii. In combination with Oxaliplatin-Containing Regimens: Dose does not exceed 1000 mg/m2 twice a day on days 1 to 14, every 21 days in combination with oxaliplatin 130 mg/m2 on day 1 of each cycle; b. Perioperative Treatment of Rectal Cancer (i or ii): i. With concomitant radiation therapy: 825 mg/m2 orally twice daily; ii. Without radiation therapy: 1,250 mg/m2 orally twice daily 10. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Gastric, Esophageal or Gastroesophageal Junction Cancer. 11. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Pancreatic Cancer. 12. Initial Approval Criteria, I.F: Created a single approval criteria for all the off label indication as "Additional NCCN Recommended Uses (off-label)". 13. Continued Therapy Approval Criteria, II.A.3: Updated to include new dosing criteria for indications, Breast Cancer, Colorectal Cancer, Pancreatic Cancer and Gastric, Esophageal or Gastroesophageal Junction Cancer.	
RxA.322.Yervoy	1. Background: Updated to include new indication Treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma, as first line treatment in combination with nivolumab. 2. Background: Updated information regarding indication melanoma from Treatment of adult patients with unresectable or metastatic melanoma, in combination with	07.01.2023

	nivolumab to Treatment of unresectable or metastatic melanoma in adults and pediatric patients 12 years and older as a single agent or in combination with nivolumab. 3. Dosing Information, Dosing Regimen, ipilimumab (Yervoy®): Updated dosing information from Combo therapy: 1 mg/kg intravenously every 6 weeks with nivolumab intravenously 3 mg/kg every 2 weeks to Combo therapy: 1 mg/kg intravenously every 6 weeks with nivolumab intravenously 360 mg every 3 weeks for indication NSCLC. 4. Dosing Information, Indication: Updated to include new indication ESCC. 5. Dosing Information, Dosing Regimen, ipilimumab (Yervoy®): Updated to include dosing information for indication ESCC. 6. Dosing Information, Maximum Dose, ipilimumab (Yervoy®): Updated to include maximum dosing information for indication ESCC. 7. Initial Approval Criteria, I.A and I.B: Updated to merge from two separate approval criteria to one approval criteria as "Melanoma". 8. Initial Approval Criteria, I.A.4: Updated prescribing criteria from Prescribed in one of the following ways (a or b): a. As a single agent; b. In combination with Opdivo®, Keytruda®, or Imlygic®,* and both of the following (i and ii): i. Member has unresectable or metastatic melanoma; ii. Age ≥ 18 years; *Prior authorization may be required for Opdivo, Keytruda, and Imlygic to Prescribed in one of the following way (a, b or c): a. As a single agent; b. In combination with Opdivo®* c. In combination with Keytruda®, or Imlygic®* and both of the following (i and ii): i. Member has unresectable or metastatic melanoma; ii. Age ≥ 18 years; d. As adjuvant treatment and member meets all of the following (i, ii and iii): i. Member has cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm; ii. Age ≥ 18 years; iii. Member had undergone complete resection, including total lymphadenectomy. 9. Initial Approval Criteria, I.B.5, I.C.4, I.E.4, I.F.4, I.G.5 and I.I.4: Updated to remove generic "nivolumab". 10. Initial Approval Criteria, I.B.6: Updated to remove prior trial and failure criteria "Member has failed fluoropyrimidine, oxaliplatin, and irinotecan treatment within the past 12	

	months, unless contraindicated or clinically significant adverse effects are experienced." 11. Initial Approval Criteria, I.C.1: Updated diagnostic criteria to remove "(Child-Pugh A only) with one of the following (a, b or c): a. Unresectable disease and the patient is not a transplant candidate; b. Inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only; c. Metastatic disease or extensive liver tumor burden 12. Initial Approval Criteria, I.D.1: Updated diagnostic criteria to remove "with no EGFR or ALK genomic tumor aberrations." 13. Initial Approval Criteria, I.D.3: Updated age criteria from Age ≥ 12 years to Age ≥ 18 years. 14. Initial Approval Criteria, I.D.4: Updated combination criteria from "Prescribed in combination with (a, b or c): a. nivolumab (Opdivo®) for PD-L1 positive NSCLC; b. nivolumab (Opdivo®), pemetrexed and either carboplatin or cisplatin (for non-squamous cell histology); c. nivolumab (Opdivo®), paclitaxel and carboplatin (for squamous cell histology); to Prescribed in combination with Opdivo®. 15. Initial Approval Criteria, I.D.5: Updated previously received drug criteria from Member has previously received Nexavar® or Lenvima®; *Prior authorization may be required for Nexavar and Lenvima to Member has previously received Nexavar®, Lenvima®, or Tecentriq® + bevacizumab or Imfinzi®. *Prior authorization may be required for Nexavar®, Lenvima®, Tecentriq®, bevacizumab and Imfinzi®. 16. Initial Approval Criteria, I.E.5: Updated to include new diagnostic criteria Request meets one of the following (a, b, c, or d): a. Disease mutation status is negative for actionable biomarkers (EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET), and member has not received prior systemic therapy for advanced disease; b. Disease mutation status is positive for EGFR S768I, L861Q, and/or G719X, and member has received prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib; c. Disease mutation status is positive for ROS1 rearrangement, and member has received prior crizotinib, entrectinib, or ceritinib; d. Disease mutation status is positive for EGFR exon 20, KRAS G12C, NRTK1/2/3, BRAF V600E, MET exon 14 skipping, or RET rearrangement. 17. Initial Approval Criteria, I.E.6.a: Updated dosing criteria	

	from Dose does not exceed 1 mg/kg intravenously every 6 weeks to Dose does not exceed 1 mg/kg intravenously every 6 weeks in combination with Opdivo®. 18. Initial Approval Criteria, I.F.3: Updated age criteria from Age ≥ 12 years to Age ≥ 18 years. 19. Initial Approval Criteria, I.G.5.a: Updated dosing criteria from Dose does not exceed 1 mg/kg/dose to Dose does not exceed 1 mg/kg/dose intravenous every 6 weeks in combination with Opdivo. 20. Initial Approval Criteria, I.H: Updated to remove approval criteria for "Neuroendocrine and Adrenal Tumors (off-label)". 21. Initial Approval Criteria, I.J: Updated to include approval criteria for Esophageal Cancer. 22. Initial Approval Criteria, I.K: Updated to include approval criteria for Ampullary Adenocarcinoma (off-label). 23. Initial Approval Criteria, I.L: Updated to include approval criteria for Bone cancer (off-label). 24. Initial Approval Criteria, I.M: Updated to include approval criteria for Malignant Peritoneal Mesothelioma (off-label). 25. Continued Therapy Approval, II.B: Merged into II.A as “Melanoma”. 26. Continued Therapy Approval, II.H: Updated to remove approval criteria for "Neuroendocrine and Adrenal Tumors (off-label)". 27. Continued Therapy Approval, II.J: Updated to include approval criteria for Esophageal Cancer. 28. Continued Therapy Approval, II.K: Updated to include approval criteria for Ampullary Adenocarcinoma (off-label). 29. Continued Therapy Approval, II.L: Updated to include approval criteria for Bone cancer (off-label). 30. Continued Therapy Approval, II.M: Updated to include approval criteria for Malignant Peritoneal Mesothelioma (off-label). 31. Appendix B, Drug Name: Updated to remove therapeutic alternatives for Neuroendocrine and Adrenal Tumors: a. carboplatin + etoposide; b. cisplatin + etoposide; c. folfox; d. Folfiri; e. nivolumab + ipilimumab; f. temozolomide + capecitabine. 32. Appendix B, Drug Name: Updated to include therapeutic alternatives for Esophageal cancer: a. oxaliplatin; b. pembrolizumab; c. irinotecan; d. nivolumab; e. ipilimumab.	

	33. Appendix B, Drug Name: Updated to include therapeutic alternatives for Ampullary Adenocarcinoma: a. nivolumab + ipilimumab; b. gemcitabine; c. 5-FU + leucovorin. 34. Appendix B, Drug Name: Updated to include therapeutic alternatives for Bone cancer: a. pembrolizumab; b. nivolumab; c. ipilimumab; d. VDC/IE (vincristine, doxorubicin, and cyclophosphamide); e. irinotecan + temozolomide ± vincristine. 35. Appendix B, Drug Name: Updated to include therapeutic alternatives for Malignant Peritoneal Mesothelioma: a. cisplatin + pemetrexed; b. nivolumab + ipilimumab; c. cisplatin + pemetrexed + bevacizumab.	
RxA.324.Yondelis	1. Dosing Information, Maximum Dose, trabectedin (Yondelis®): Updated to maximum dosing information from Varies to 1.5 mg/m^2 intravenously every 3 weeks for indication LPS & LMS. 2. Appendix D: Updated to remove angiosarcoma.	07.01.2023
RxA.327.Zaltrap	1. Appendix B, Dosing Regimen, CapeOX: Updated dosing information from Days 1–14: Capecitabine 1,000 mg/m2 orally twice daily. Repeat cycle every 3 weeks to Days 1–14: Capecitabine 1,000 mg/m2 orally twice daily. Repeat cycle every 3 weeks for indication Colorectal cancer.	07.01.2023
RxA.330.Zinplava	1. Initial Approval Criteria I.A.4: Updated from two episodes to one episode and a total of three episodes to total of two episodes.	07.01.2023
RxA.331.Aczone	1. Dosage Forms: Updated dosage form from Gel tube (60 g, 90 g): 5% and Gel pump (60 g, 90 g): 7.5% to Gel tube (30 gm, 60 gm, 90 gm): 5% and Gel pump (30 gm, 60 gm, 90 gm): 7.5%.	07.01.2023
RxA.332.Adcirca_Alyq_Tadliq	1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Tadliq®. 2. Background: Updated to include new Brand, Tadliq®. 3. Dosing Information, Drug Name: Updated to include new drug Tadliq®. 4. Dosing Information, Dosing Regimen, tadalafil (Adcirca®, Alyq™, Tadliq®): Updated to include hepatic and renal impairment dosing information for indication PAH. 5. Dosage Forms: Updated to include new brand dosage form, Tadliq®: Oral suspension: 20 mg/5 mL. 6. Initial Approval Criteria, I.A.4: Updated to remove prior trial and failure criteria "If request is for brand Adcirca® or Alyq™, member must use generic tadalafil, unless	07.01.2023

	contraindicated or clinically significant adverse effects are experienced." 7. Initial Approval Criteria, I.A.4: Updated to include new drug request criteria, For Tadliq® request, member is unable to swallow tablets. 8. Continued Therapy Approval Criteria, II.A.3: Updated to remove prior trial and failure criteria "If request is for brand Adcirca® or Alyq™, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced." 9. Continued Therapy Approval Criteria, II.A.3: Updated to include new drug request criteria, For Tadliq® request, member is unable to swallow tablets. 10. Appendix A: Updated to include abbreviations GC & PDE5. 11. Appendix B, Dosing Regimen, amlodipine (Norvasc®): Updated dosing information from initial, 2.5 mg orally once daily to 5 mg orally once daily for indication PAH. 12. Appendix B, Maximum Dose, amlodipine (Norvasc®): Updated maximum dose information from 20 mg/day to 10 mg/day for indication PAH. 13. Appendix D, General Information: Updated to include new information regarding Renal Impairment and Hepatic Impairment.	
RXA.335.Alecensa	1. Initial Approval Criteria, I.B.6.a: Updated to remove prior dosing criteria "Dose does not exceed 1,200 mg (8 capsules) per day". 2. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Uterine Neoplasms. 3. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Histiocytic Neoplasms – Erdheim-Chester Disease.	07.01.2023
RxA.347.Oncaspar_Asparlas	1. Initial Approval Criteria, I.A.3: Updated to include new age criteria If request is for Asparlas®, age 1 month to ≤ 21 years. 2. Initial Approval Criteria, I.A.4: Updated to include new prescribing criteria Prescribed as part of a multi-agent chemotherapeutic regimen. 3. Initial Approval Criteria, I.B.1: Updated diagnosis criteria from Diagnosis of one of the following NK/T-cell lymphoma subtypes (a, b, or c): a. Nasal type; b. Extranasal type; c. Aggressive NK-cell leukemia to Diagnosis of one of the following (a or b): a. Extranodal NK/T-cell lymphoma; b. Hepatosplenic T-cell lymphoma 4. Initial Approval Criteria, I.C: Updated approval criteria to	07.01.2023

	merge into one as Extranodal NK/T-Cell Lymphoma (off-label) (I.B).	
RxA.349.Austedo_Austedo XR	1. Drug(s) Applied, Background, Dosing information: Updated to include information for new brand Austedo® XR. 2. Dosage Forms: Updated to include new dosage form, Extended-release tablets: 6 mg, 12 mg, and 24 mg.	07.01.2023
RxA.350.Alimta_Pemfexy	1. Background was updated to include indication In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR (Epidermal growth factor receptor) or ALK (Anaplastic lymphoma kinase) genomic tumor aberrations for Pemfexy™. 2. Initial Approval Criteria, I.B.5 : Updated prescribing regimen criteria from Prescribed as second-line therapy (initial treatment may include surgery, radiation therapy, chemotherapy); to Member meets any one of the followings (a or b) a. Prescribed as first line therapy or postoperative treatment in patients who are unable to tolerate first-line combination regimens; b. Prescribed as second-line therapy for unresectable or metastatic disease. 3. Initial Approval Criteria. I.C.5: Updated to add prescribed as a single agent. 4. Initial Approval Criteria, I.E: Updated to include new off label Indication.	07.01.2023
RxA.431.Opdivo	1. Background: Updated indication from to Melanoma: • Patients with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab; • Patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting to • Adult and pediatric (12 years and older) patients with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab. • Adult and pediatric (12 years and older) patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting. 2. Dosing Information, Dosing Regimen, nivolumab (Opdivo®): Updated dosing information from to Monotherapy: 240 mg intravenous every 2 weeks or 480 mg intravenous every 4 weeks to Weight 40 kg or greater: Monotherapy, Adjuvant treatment: 240 mg intravenous every 2 weeks or 480 mg intravenous every 4 weeks for indication Melanoma. 3. Dosing Information, Maximum Dose, nivolumab (Opdivo®): Updated to maximum dosing information from 480 mg/dose to Weight 40 kg or greater: 480 mg every 4 weeks for indication Melanoma.	07.01.2023

	4. Dosing Information, Maximum Dose, nivolumab (Opdivo®): Updated to maximum dosing information from with ipilimumab: 1mg/kg/dose to with ipilimumab: 1 mg/kg every 3 weeks for indication Melanoma. 5. Dosing Information, Dosing Regimen, nivolumab (Opdivo®): Updated to include dosing information for pediatrics indication Melanoma. 6. Dosing Information, Maximum Dose, nivolumab (Opdivo®): Updated to include maximum dosing information for pediatrics for indication Melanoma. 7. Initial Approval Criteria, I.A.3: Updated age criteria from Age ≥ 18 years to Age ≥ 12 years. 8. Initial Approval Criteria, I.A.4.a: Updated dosing criteria from Monotherapy: Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks to Monotherapy (unresectable or metastatic disease or adjuvant treatment): Dose does not exceed one of the following (i or ii): i. Adult and Pediatrics (Weight 40 kg or greater): 480 mg every 4 weeks; ii. Pediatrics (Weight less than 40 kg): 6 mg/kg every 4 weeks. 9. Initial Approval Criteria, I.A.4.b: Updated dosing criteria from In combination with Yervoy®: Dose does not exceed 1 mg/kg every 3 weeks for 4 doses, followed by 240 mg every 2 weeks or 480 mg every 4 weeks to In combination with Yervoy® (unresectable or metastatic disease): Dose does not exceed one of the following (i or ii): i. Adult and Pediatrics (Weight 40 kg or greater): 1 mg/kg intravenous, followed by 3 mg/kg intravenous on the same day, every 3 weeks for 4 doses, then 240 mg intravenous every 2 weeks or 480 mg intravenous every 4 weeks; ii. Pediatrics (Weight less than 40 kg): 1 mg/kg intravenous, followed by 3 mg/kg intravenous on the same day, every 3 weeks for 4 doses, then 3 mg/kg intravenous every 2 weeks or 6 mg/kg intravenous every 4 weeks. 10. Initial Approval Criteria, I.D.3: Updated diagnostic criteria from Diagnosis of cHL to Diagnosis of relapsed, refractory or progressive cHL. 11. Initial Approval Criteria, I.D.4: Updated to include new combination therapy criteria Prescribed as subsequent therapy. 12. Initial Approval Criteria, I.E.4: Updated to include new prescribing criteria Prescribed as a single agent. 13. Initial Approval Criteria, I.F.4.c: Updated to include criteria pertaining to indication Urothelial Carcinoma, "Member is at high risk of recurrence and did not previously receive a platinum containing regimen".	

	14. Initial Approval Criteria, I.H.6: Updated to include new documentation criteria Documentation of Child-Pugh Class A status. 15. Initial Approval Criteria, I.I.1: Updated diagnostic criteria from to Diagnosis of unresectable advanced, recurrent or metastatic ESCC to Diagnosis of one of the following (a or b): a. Completely resected esophageal cancer or gastroesophageal junction (esophagogastric junction; EGJ) cancer; b. Unresectable advanced, recurrent, or metastatic ESCC. 16. Initial Approval Criteria, I.I.5: "Opdivo® can be used as (a or b): a. As first-line treatment in combination with fluoropyrimidine- and platinum containing chemotherapy; b. As first-line treatment in combination with Yervoy®;" was replaced with For ESCC, one of the following (a or b): a. For unresectable advanced or metastatic disease: Prescribed in combination with Yervoy or with fluoropyrimidine- and platinum-containing chemotherapy; b. For unresectable advanced, recurrent, or metastatic disease: Member has had previous treatment with a fluoropyrimidine-based (e.g., 5-fluorouracil, capecitabine) and platinum-based (e.g., carboplatin, cisplatin, oxaliplatin) chemotherapy. 17. Initial Approval Criteria, I.I.7.b: Updated to include new dosing criteria ESCC In combination with Yervoy®: Dose does not exceed 3 mg/kg every 2 weeks or 360 mg every 3 weeks. 18. Initial Approval Criteria, I.J.1: Updated diagnostic criteria from Request is for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma, in combination with Yervoy® to Diagnosis of unresectable malignant pleural mesothelioma. 19. Initial Approval Criteria, I.J.4: Updated to include new combination therapy criteria Prescribed in one of the following ways (a or b): a. As first-line therapy in combination with Yervoy®; b. If not administered first-line, as subsequent therapy in combination with Yervoy or as a single agent. 20. Initial Approval Criteria, I.K.2: Updated to include new diagnostic criteria Member meets one of the following (a or b): a. Disease is advanced, recurrent, or metastatic; b. For EGJ cancer or esophageal adenocarcinoma: member meets one of the following (i or ii):	

	i. Member is post-operative following chemoradiation; ii. Disease is advanced, recurrent, or metastatic. 21. Initial Approval Criteria, I.k.5: Updated to include new combination therapy criteria For advanced, recurrent, or metastatic disease: both of the following are met (a and b): a. Prescribed in combination with a fluoropyrimidine- (e.g., 5-fluorouracil, capecitabine) and platinum-containing (e.g., carboplatin, cisplatin, oxaliplatin) chemotherapy; b. Disease is HER2-negative. 22. Initial Approval Criteria, I.L.1: Updated to include new diagnostic criteria: • Central nervous system cancer (e.g., Brain metastases); • Bone cancer; • Kaposi Sarcoma; • Kidney cancer (e.g.; Clear cell and Non clear cell) • Pediatric primary mediastinal large B-cell lymphoma; • Pediatric diffuse high-grade gliomas; • Soft tissue sarcoma (e.g.; Rhabdomyosarcoma, Angiosarcoma); • Colon cancer; • Biliary Tract cancer. 23. Initial Approval Criteria, I.L.3.b: Updated dosing criteria from For Pediatric Hodgkin lymphoma: Age ≤ 18 years to For Pediatric Hodgkin lymphoma, Pediatric primary mediastinal large B-cell lymphoma, Pediatric diffuse high-grade gliomas: Age ≤ 18 years. 24. Continued Approval Criteria, II.A.3: Updated dosing criteria from New dose does not exceed 480 mg every 4 weeks to a. NSCLC in combination with Yervoy®: New dose does not exceed 3 mg/kg every 2 weeks; b. Malignant pleural mesothelioma in combination with Yervoy, and gastric and esophageal adenocarcinomas: New dose does not exceed 360 mg every 3 weeks; c. ESCC in combination with Yervoy: New dose does not exceed 3 mg/kg every 2 weeks or 360 mg every 3 weeks; d. Other indication: New dose does not exceed240 mg every 2 weeks or 480 mg every 4 weeks. 25. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. Lenvima®; b. Imfinzi®.	
RxA.463.Rubraca	1. Background: Updated to include details regarding indication recurrent epithelial ovarian, fallopian tube, or primary	07.01.2023

	peritoneal cancer "a deleterious BRCA mutation (germline and/or somatic)- associated". 2. Initial Approval Criteria, I.A.5: Updated to include new requesting criteria a. Both i and ii: i. Documentation of deleterious or suspected deleterious BRCA mutation; ii. Completed 2 platinum-based chemotherapy regimens and is in a complete or partial response; b. Both i and ii: i. Newly diagnosed stage II-IV disease (see Appendix D); ii. Completed first-line platinum-based chemotherapy regimen and is in a complete or partial response;. 3. Initial Approval Criteria, I.B.8: Updated to include new prior therapy criteria Member has not previously received a PARP inhibitor (e.g., Lynparza®, Talzenna®, Zejula®) (see Appendix D).	
RxA.467.Revatio	1. Background: Updated to remove detail pertaining to indication pulmonary arterial hypertension (PAH), "The delay in clinical worsening was demonstrated when Revatio® was added to background epoprostenol therapy. Studies establishing effectiveness were short-term (12 to 16 weeks) and included predominately patients with New York Heart Association (NYHA) Functional Class II-III symptoms and idiopathic etiology (71%) or associated with connective tissue disease (25%)." 2. Background: Updated to remove limitation(s) of use, “Limitation(s) of use: Adding sildenafil to bosentan therapy does not result in any beneficial effect on exercise capacity.” 3. Background: Updated to include new information regarding Pediatric Patients (1 to 17 years old), "Sildenafil (Revatio®) is indicated in pediatric patients 1 to 17 years old for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise." 4. Dosing Information, Dosing Regimen, sildenafil (Revatio®): Updated dosing information from Tablet and oral suspension: 5 mg or 20 mg Orally three times a day, 4-6 hours apart Injection: 2.5 mg or 10 mg three times a day as an Intravenous bolus to Adults: Tablet and oral suspension: 20 mg orally three times a day Injection: 10 mg three times a day as an Intravenous bolus for indication Pulmonary arterial hypertension. 5. Dosing Information, Maximum Dose, sildenafil (Revatio®): Updated to maximum dosing information from Tablet/oral suspension: 60 mg/day to Tablet/oral suspension: 240	07.01.2023

	mg/day for indication Pulmonary arterial hypertension. 6. Dosing Information, Dosing Regimen and Maximum Dose, sildenafil (Revatio®): Updated to include dosing information for ages Pediatrics (1 to 17 years old) for indication Pulmonary arterial hypertension. 7. Initial Approval Criteria, I.A.4: Updated dosing criteria from Dose does not exceed 60 mg per day (oral formulations) or 30 mg per day (intravenous formulations) in divided doses to Dose does not exceed any one of the following (a, b or c): a. For adults (orally): 80 mg/day three times a day; b. For adults (Intravenously): 30 mg/day; c. Pediatrics weight-based dose (1 to 17 years old): i. Weighing ≤ 20 kg: 10 mg three times a day; ii. Weighing 20 kg to 45 kg: 20 mg three times a day; iii. Weighing > 45 kg: 40 mg three times a day. 8. Continued Therapy Approval Criteria, II.A.3: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 60 mg per day (oral formulations) or 30 mg per day (intravenous formulations) in divided doses to Dose does not exceed any one of the following (a, b or c): a. For adults (orally): 80 mg/day three times a day; b. For adults (Intravenously): 30 mg/day; c. Pediatrics weight-based dose (1 to 17 years old): i. Weighing ≤20 kg: 10 mg three times a day; ii. Weighing 20 kg to 45 kg: 20 mg three times a day; iii. Weighing >45 kg: 40 mg three times a day. 9. Appendix B: Updated to remove brands Adalat CC and Procardia due to discontinuation.	
RxA.472.Sunosi	1. Background: Updated indication from Solriamfetol (Sunosi®) is a wakefulness promoting agent to Solriamfetol (Sunosi®) is a dopamine and norepinephrine reuptake inhibitor (DNRI). 2. Dosing Information, Dosing Regimen, solriamfetol (Sunosi®): Updated to remove for indication Narcolepsy and OSA hepatic impairment dosing information Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed. 3. Appendix D, General Information: Updated to include new information regarding End stage renal disease (ESRD) dosing.	07.01.2023
RxA.528.Tecentriq	1. Background: Updated to remove indication Urothelial Carcinoma. 2. Background: Updated to Include indication ASPS.	07.01.2023

	3. Dosing Information, Dosing Regimen and Maximum Dose Tecentriq®: Updated to remove dosing information for indication Urothelial Carcinoma. 4. Dosing Information, Dosing Regimen and Maximum Dose Tecentriq®: Updated to include dosing information for indication ASPS. 5. Initial Approval Criteria, I.A: Updated to remove approval criteria for Urothelial Carcinoma. 6. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, ASPS. 7. Continued Therapy Approval, II.A.3.b: Updated to include new dosing criteria Pediatrics ≥ 2 years: 15 mg/kg every 3 weeks; 8. Appendix B, Drug Name: Updated to remove therapeutic alternatives, cisplatin, oxaliplatin or carboplatin-containing chemotherapy. 9. Appendix D, General Information: Updated to include new information regarding ECOG score.	
RxA.531.Tymlos	1. Background: Updated to include expanded indication for treatment in males as well as postmenopausal females. 2. Background: Removed statement "In postmenopausal women with osteoporosis, Tymlos® reduces the risk of vertebral fractures and nonvertebral fractures." 3. Dosing Information, Indication: Updated to include expanded indication for treatment in males. 4. Initial Approval Criteria, I.A.1.a: Updated indication from Diagnosis of Postmenopausal women with osteoporosis to Diagnosis of postmenopausal or male osteoporosis. 5. Initial Approval Criteria, I.A.3: Removed criteria, Member is a postmenopausal female.	07.01.2023
RxA.532.Tysabri	No updates	07.01.2023
RxA.572.Zepatier	1. Dosing Information, Dosing Regimen, Zepatier®: Updated dosing information to replace "Zepatier®" with "grazoprevir 100 mg/ elbasvir 50 mg" for all genotypes. 2. Appendix B, Drug Name: Updated to include new therapeutic alternative sofosbuvir/ velpatasvir (Epclusa®).	07.01.2023
RxA.573.Zejula	1. Background: Updated to remove indication "For the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: • deleterious or suspected deleterious BRCA mutation, or • genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy." 2. Background: Updated to include details regarding indication	07.01.2023

	recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer "deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut)". 3. Dosing Information, Indication: Updated to include new indication Deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. 4. Initial Approval Criteria, I.A.1: Updated diagnostic criteria to Diagnosis of advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. 5. Initial Approval Criteria, I.A.1.c: Updated diagnostic criteria to remove "Disease is associated with HRD positive status defined by one of the following (a or b): a. Documentation of deleterious or suspected deleterious germline BRCA mutation; b. Documentation of genomic instability and disease has progressed > 6 months after response to the last platinum-based chemotherapy; c. Failure of ≥ 3 prior chemotherapy regimens (see Appendix B), unless contraindicated or clinically significant adverse effects are experienced; 6. Initial Approval Criteria, I.A.4: Updated to include new criteria Members request meets one of the following (a or b): a. Both i and ii: i. Newly diagnosed stage II-IV disease; ii. Completed first-line platinum-based chemotherapy regimen and is in a complete or partial response; b. Both i and ii (see Appendix F): i. Documentation of deleterious or suspected deleterious germline BRCA-mutation; ii. Completed platinum-based chemotherapy and is in a complete or partial response 7. Initial Approval Criteria, I.A.5: Updated to include new prior therapy criteria Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Talzenna®). 8. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Uterine Cancer. 9. Initial Approval Duration for all indications: Updated from 6 months to 12 months. 10. Appendix D, General Information: Updated to include new information regarding: a. Restricted Second or Later Line Setting Indication to Germline BRCA Mutated Population. b. Insufficient data regarding use of PARP inhibitors.	
RxA.591.Botox	1. Initial Approval Criteria, I.A.7, I.B.6, I.C.5, I.D.4, I.E.7, I.F.6, I.G.6, I.H.6, I.I.6, I.J.6, I.K.5 and I.L.5: Updated to	07.01.2023

	include new requesting criteria Member meets both of the following (a and b): a. Botox is not prescribed concurrently with other botulinum toxin products; b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks; 2. Initial Approval Criteria, 1.G.3: Updated age criteria from Age ≥ 18 years of age to Age ≥ 5 years; 3. Continued Therapy Approval Criteria, II.A.7, II.B.5 and II.C.5: Updated to include new requesting criteria Member meets both of the following (a and b): a. Botox is not prescribed concurrently with other botulinum toxin products; b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;	
RxA.600.Nucala	1. Initial Approval Criteria, I.B.1 Updated diagnosis criteria From Diagnosis of EGPA (Churg-Strauss) to Diagnosis of EGPA (Churg-Strauss) defined as presence of all of the following (a, b, and c): a. Asthma; b. At least 2 of the following characteristics of EGPA: histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation; neuropathy; pulmonary infiltrates; sino-nasal abnormality; cardiomyopathy; glomerulonephritis; alveolar hemorrhage; palpable purpura; or antineutrophil cytoplasmic antibody (ANCA) positivity; c. Member has an absolute blood eosinophil count ≥ 150 cells/mcL within the last 3 months; 2. Initial Approval Criteria, I.B.4: Updated to include new diagnostic criteria Member meets one of the following (a or b): a. Member has experienced at least 1 relapse in the past 2 years while receiving a glucocorticoid, which required an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization; b. Member has refractory disease in the past 6 months, defined as either (i or ii): i. Failure to achieve remission following ≥ 3 month trial of a standard induction regimen (e.g., glucocorticoids, cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil); ii. Recurrence of EGPA symptoms during glucocorticoid dose taper; 3. Initial Approval Criteria, I.D.8: Updated to include new concurrent therapy criteria Nucala is prescribed	07.01.2023

	concurrently with baseline HES therapy (e.g., oral corticosteroids, immunosuppressive therapy); 4. Continued Therapy Criteria, II.D.3: Updated to include new concurrent therapy criteria Nucala is prescribed concurrently with baseline HES therapy (e.g., oral corticosteroids, immunosuppressive therapy); 5. Appendix B, Dosing Regimen, methylprednisolone (Medrol): Updated dosing information from 6.0 mg/day to 0.8 mg/kg/day to 4 to 48 mg/day orally, administered in 4 divided doses for indication EGPA. 6. Appendix B, Dosing Regimen, prednisone: Updated dosing information from 7.5 mg/day to 1 mg/kg/day to 5 to 60 mg/day orally in 1 to 4 divided doses for indication EGPA.	
RxA.611.Libtayo	1. Background: Updated to include new information regarding NSCLC, "In combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or ROS1 aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.". 2. Background: Updated to include detail(s) regarding indication NSCLC, "As a single agent for first-line treatment of patients with non-small cell lung cancer (NSCLC)". 3. Initial Approval Criteria, I.C.2: Updated to include “for locally advanced and metastatic disease”: Members are not candidates for surgical resection or definitive chemoradiation. 4. Initial Approval Criteria, I.C.6: Updated to include new diagnostic criteria Prescribed in one of the following ways (a, b, or c): a. As a single agent, and one of the following (i or ii): i. Tumor has high PD-L1 expression (TPS ≥ 50%); ii. Tumor has PD-L1 expression < 50%, and therapy is prescribed following first-line therapy with Libtayo® combination therapy (e.g., cemiplimab-rwlc, [pemetrexed or paclitaxel], and [carboplatin or cisplatin]); b. In combination with platinum-based chemotherapy (e.g., cisplatin carboplatin); c. In combination with pemetrexed as continuation maintenance therapy following first-line therapy with Libtayo® combination therapy for nonsquamous cell tumors	07.01.2023
RxA.620.Brukinsa	1. Background: Updated to include new indication Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). 2. Dosing Information, Indication: Updated to include new indication Chronic lymphocytic leukemia (CLL) or small	07.01.2023

	lymphocytic lymphoma (SLL). 3. Dosing Information, Maximum Dose, zanubrutinib (Brukinsa®): Updated to include maximum dosing information for indication MCL, WM, MZL, CLL, SLL.Initial Approval Criteria, I.A: Updated indication from B-Cell Lymphoma to Mantle Cell Lymphoma. 4. Initial Approval Criteria, I.A.1: Updated diagnosis criteria from Member has one of the following types of B-cell lymphoma diagnosis: a. Mantle cell lymphoma; b. Gastric MALT Lymphoma; c. Non-gastric MALT lymphoma (non-cutaneous) to Diagnosis of Mantle Cell Lymphoma. 5. Initial Approval Criteria, I.A.4: Updated to include new disease progression criteria If disease is positive for BTK C481S mutation: Member has not had previous disease progression on Imbruvica®. 6. Initial Approval Criteria, I.A.6.b, I.B.5.b and I.C.6.b and I.D.6.b: Updated to include new dosing criteria If co-administered with a moderate CYP3A4 inducer (e.g., bosentan, efavirenz, phenobarbital, primidone), dose does not exceed 640 mg per day. 7. Initial Approval Criteria I.A, I.B, I.C and I.D: Updated Approval Duration criteria for commercial from 6 months to 12 months. 8. Initial Approval Criteria, I.B.4: Updated combination therapy criteria from Brukinsa® is not prescribed concurrently with Imbruvica® to Brukinsa® is not prescribed concurrently with Imbruvica® or Calquence®. 9. Initial Approval Criteria, I.B.5: Updated to remove prior criteria pertaining to indication Waldenström's Macroglobulinemia, " Brukinsa® will be used as single agent for one of the following (a, b, or c): a. For primary therapy; b. Request to be considered for relapse if previously used as primary therapy that was well tolerated and elicited a prolonged response; c. Request is to be used as alternative therapy for previously treated disease that does not respond to primary therapy or for progressive or relapsed disease; d. For the management of symptomatic Bing-Neel syndrome." 10. Initial Approval Criteria, I.C.1: Updated indication from Diagnosis of relapsed or refractory Marginal Zone Lymphoma to Diagnosis of one of the following MZL subtypes (a, b, c, or d): a. Gastric MALT lymphoma; b. Nongastric MALT lymphoma; c. Nodal MZL; d. Splenic MZL;	

	11. Initial Approval Criteria, I.D: Updated from off label indication to labelled indication. 12. Initial Approval Criteria, I.D.3: Updated to remove prior prescribing criteria "Prescribed as monotherapy for one of the following (a or b): a. CLL/SLL with del(17p)/TP53 mutation in members with contraindication to other bruton tyrosine kinase (BTK) inhibitors who have indications for treatment; b. CLL/SLL with or without del(17p)/TP53 mutation in patients with intolerance or contraindication to other BTK inhibitors who have indications for retreatment" 13. Initial Approval Criteria, I.D.4: Updated to include new prescriber criteria Prescribed as single agent therapy. 14. Initial Approval Criteria, I.D.5: Updated to include new disease progression criteria If disease is positive for BTK C481S mutation: Member has not had previous disease progression on Imbruvica. 15. Initial Approval Criteria, I.D.7: Updated to remove prior intolerance criteria "Member has intolerance or contraindication to other BTK inhibitors (e.g., ibrutinib, acalabrutinib)." 16. Continued Therapy Approval: Updated Approval Duration criteria from 6 months to 12 months. 17. Appendix B, Maximum Dose, Imbruvica®: Updated maximum dose information from 560 mg/day to 420 mg/day for indication CLL/SLL and Waldenström's Macroglobulinemia. 18. Appendix B, Dosing Regimen, Imbruvica®: Updated dosing information from 560 mg once daily; continue until disease progression or unacceptable toxicity to 420 mg orally once daily for indication Waldenström's Macroglobulinemia.	
RxA.624.Oxbryta	1. Dosage Forms: Updated to include new dosage form, Tablet: 300mg. 2. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from The member has a diagnosis of sickle cell disease (homozygous hemoglobin S, sickle hemoglobin C disease, hemoglobin Sβ-thalassemia, or other genotypic variants of sickle cell disease) to Diagnosis of SCD with one of the following genotypes (a, b, c or d); a. Homozygous hemoglobin S; b. Hemoglobin Sβ0 thalassemia; c. Hemoglobin Sβ+ thalassemia; d. Hemoglobin SC. 3. Initial Approval Criteria, I.A.6: "Member has had at least one prior vaso-occlusive crisis (VOC) in the previous 12 months" was replaced with Member meets one of the following (a or b): a. Member has experienced at least 1 vaso-occlusive crisis (VOC) within the past 6 months while on hydroxyurea at up to maximally indicated doses (see	07.01.2023

	Appendix D); b. Member has intolerance or contraindication to hydroxyurea and has experienced at least 1 VOC within the past 12 months (see Appendix D). 4. Initial Approval Criteria, I.A.8: Updated to include new trial and failure criteria For age ≥ 5 years: Trial and failure of L-glutamine at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced. 5. Initial Approval Criteria, I.A.9: Updated to include new trial and failure criteria For age ≥ 16 years: Trial and failure of a 6-month trial of Adakveo®, unless contraindicated or clinically significant adverse effects are experienced. 6. Initial Approval Criteria, I.A.10: Updated to include new trial and failure criteria Trial and failure of blood transfusion(s), unless contraindicated or clinically significant adverse effects are experienced (e.g., cutaneous ulcers, iron overload). 7. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative hydroxyurea. 8. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. Endari®; b. Adakveo®. 9. Appendix D, General Information: Updated to include new information regarding VOC and Myelosuppression and hydroxyurea treatment failure.	
RxA.630.Ubrelvy	1. Appendix C, Contraindications: Updated to include new contraindication, History of serious hypersensitivity to ubrogepant or any component of Ubrelvy®. 2. Appendix B, Maximum Dose, Emgality®: Updated maximum dose information from 120 mg to 300 for indication migraine.	07.01.2023
RxA.634.Trodelvy	1. Background: Updated to include detail(s) regarding indication breast cancer, Unresectable locally advanced or metastatic hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine based therapy and at least two additional systemic therapies in the metastatic setting. 2. Dosing Information, Indication: Updated to include new indication Unresectable locally advanced or metastatic hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer. 3. Initial Approval Criteria, I.A.1.a: Updated to include new criteria pertaining to indication breast cancer, b. Hormone receptor (HR)- positive, human epidermal growth factor	07.01.2023

	receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer. 4. Initial Approval Criteria, I.A.4.b: Updated to include new criteria pertaining to indication breast cancer b. For Hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer: Received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. 5. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative: a. eribulin b. Ixabepilone c. atezolizumab d. pembrolizumab e. nivolumab f. avelumab 6. Appendix C, Boxed Warnings: Updated to remove boxed warning, administer atropine, if not contraindicated, for early diarrhoea of any severity. 7. Appendix D, General Information: Updated to include new information regarding ECOG Performance Status Scale.	
RxA.637.Fasenra	1. Initial Approval Criteria, I.A.5: Updated criteria pertaining to indication from Member has experienced ≥ 1 exacerbations to Member has experienced ≥ 2 exacerbations. 2. Appendix B, Drug Name: Updated to remove discontinued therapeutic alternatives: a. beclomethasone (QVAR®); b. Flovent®; c. Serevent®; d. Dexamethasone (Decadron®) oral tablets. 3. Appendix B, Drug Name: Updated to include generic therapeutic alternative fluticasone furoate/vilanterol trifenatate.	07.01.2023
RxA.638.DarzalexFaspro_ Darzalex	1. Dosing Information, Dosing Regimen, daratumumab (Darzalex®): Updated dosing information from Week 25 onwards until disease progression - every four weeks (First dose of the every-4-week dosing schedule is given at Week 55) to Week 55 onwards until disease progression - every four weeks (First dose of the every-4-week dosing schedule is given at Week 55) for indication Multiple Myeloma (In combination with bortezomib, melphalan and prednisone ([VMP], 6-Week Cycle)). 2. Dosing Information, Dosing Regimen, daratumumab (Darzalex®): Updated dosing information from With carfilzomib and dexamethasone (4-Week Cycle) Week 1: 8 mg/kg every 1 and 2 (total of 2 dose) to With carfilzomib and dexamethasone (DKd) (4-Week Cycle) Week 1: 8 mg/kg	07.01.2023

	every day 1 and 2 (total of 2 dose) for indication Multiple Myeloma (With carfilzomib and dexamethasone (DKd) (4-Week Cycle). 3. Initial Approval Criteria, I.A.4.a.ii.b), I.A.4.a.ii.c) and I.A.4.a.ii.d): Updated to include new combination therapy criteria a. bortezomib*, lenalidomide*, and dexamethasone; b. bortezomib*, cyclophosphamide, dexamethasone; c. carfilzomib*, lenalidomide*, and dexamethasone. 4. Appendix B, Drug Name: Updated to include generic therapeutic alternative lenalodomide. 5. Appendix B, Maximum Dose, Thalomid®: Updated to remove maximum dose information for indication Erythema nodosum leprosum.	
RxA.647.Tukysa	1. Background: Updated to include new indication Unresectable or Metastatic Colorectal Cancer. 2. Dosing Information, Indication: Updated to include new indication Unresectable or Metastatic Colorectal Cancer. 3. Dosing Information, Dosing Regimen, Tukysa®: Updated to include dosing information for indication Unresectable or Metastatic Colorectal Cancer. 4. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Unresectable or Metastatic Colorectal Cancer. 5. Appendix B, Drug Name: Updated to include therapeutic alternatives for Breast and Colorectal cancer.	07.01.2023
RxA.649.Zeposia	1. Initial Approval Criteria, I.B.5: Updated trial and failure criteria to include new preferred brand, Amjevita™.	07.01.2023
RxA.673.Rituximab	1. Initial Approval Criteria, I.D.7.a.i and I.D.7.a.ii: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.677.Amondys 45	1. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria Member has a stable cardiac function (left ventricular ejection fraction [LVEF] ≥ 40%) and pulmonary function (forced vital capacity [FVC] ≥ 50% predicted). 2. Appendix B, Drug Name: Updated to include new therapeutic alternatives a. prednisone* b. Emflaza® 3. Appendix D, General Information: Updated to include new information regarding warnings and precautions.	07.01.2023
RxA.678.Evkeeza	1. Background: Updated information regarding Age from Evkeeza® is an ANGPTL3 (angiopoietin-like 3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH) to Evkeeza® is an ANGPTL3 (angiopoietin-like 3) inhibitor indicated as an adjunct to other low-density lipoprotein-	07.01.2023

	cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH). 2. Initial Approval Criteria, I.A.2: Updated age criteria from Member is ≥ 12 years of age to Age ≥ 5 years. 3. Initial Approval Criteria, I.A.5: Updated to include new requesting criteria Member meets one of the following (a or b): a. Member meets both of the following (i and ii) i. Member has tried one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor for ≥ 8 continuous weeks; ii. The low-density lipoprotein cholesterol (LDL-C) level after this PCSK9 inhibitor therapy remains ≥ 70 mg/dL; b. Member is known to have two LDL-receptor negative alleles; 4. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. ezetimibe/simvastatin (Vytorin®) b. ezetimibe (Zetia®) c. atorvastatin (Lipitor®) d. rosuvastatin (Crestor®) e. pravastatin f. fluvastatin (Lescol®) g. Praluent®	
RxA.681.Tepmetko	1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of advanced NSCLC with MET exon 14 skipping alterations to Diagnosis of recurrent, advanced or metastatic NSCLC with MET exon 14 skipping alterations. 2. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria Disease is positive for a mutation causing MET exon 14 skipping or high-level MET amplification. 3. Appendix D, General Information: Updated to include new information regarding MET amplification.	07.01.2023
RxA.682.Cosela	1. Initial Approval Criteria, I.A.6: Updated to include new combination therapy criteria Cosela™ will not be used concomitantly with colony stimulating factors (e.g., G-CSF, peg-G-CSF, GM-CSF, etc) for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy.	07.01.2023
RxA.683.Fotivda	1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from diagnosis of advanced renal cell carcinoma to Diagnosis of relapsed or refractory advanced renal cell carcinoma with clear cell histology. 2. Initial Approval Criteria, I.A.5: Updated to include new prescribing criteria Fotivda® will be prescribed as single agent. 3. Initial Approval Criteria, I.A.6: Updated to include new criteria pertaining to indication Relapsed, Refractory	07.01.2023

	Advanced Renal Cell Carcinoma, Member must not have had a surgical procedure within the preceding 24 days or have a surgical wound that has not fully healed. 4. Initial Approval Criteria, I.A.7: Updated to include new disease progression criteria Member does not have unstable or untreated central nervous system (CNS) metastases. 5. Appendix B, Drug Name: Updated to remove therapeutic alternatives: a. Proleukin®; b. temsirolimus (Torisel®); c. Avastin®; d. sorafenib (Nexavar®). 6. Appendix B, Drug Name: Updated to include generic therapeutic alternative sorafenib. 7. Appendix B, Drug Name: Updated to remove generic therapeutic alternative bevacizumab.	
RxA.684.Nulibry	No updates	07.01.2023
RxA.685.Jemperli	1. Background: Updated information regarding indication endometrial cancer from Endometrial cancer, to include “in any setting and are not candidates for curative surgery or radiation.” 2. Dosing Information, Indication: Solid tumor updated to Recurrent/advanced solid tumor with dMMR. 3. Initial Approval Criteria, I.A.4 and I.B.6: Updated to include new prescribing criteria Jemperli® will be prescribed as a single agent. 4. Initial Approval Criteria, I.A.6: Updated to include new criteria for indication Endometrial Cancer, Member is not a suitable candidate for curative surgery or radiation. 5. Initial Approval Criteria, I.B.1: Updated diagnosis from solid tumor to recurrent or advanced solid tumor with dMMR. 6. Initial Approval Criteria, I.B.1: Updated to remove prior diagnostic criteria "Hepatobiliary cancer". Also to include new diagnostic criteria ampullary adenocarcinoma, esophageal and esophagogastric junction cancers. 7. Initial Approval Criteria, I.B.4 was removed for, Disease is recurrent or advanced, dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression), since criteria was added into initial approval criteria I.B.1.	07.01.2023
RxA.687.Zynlonta	1. Initial Approval Criteria, I.A.6.a: Updated to include “Dose does not exceed 0.15 mg/kg intravenously every 3 weeks for 2 cycles, then 0.075 mg/kg every 3 weeks for subsequent cycles”. 2. Initial Approval Criteria, I.A.6.b: Updated to include new dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). 3. Initial Approval Criteria, I.B: Updated to be removed.	07.01.2023

	4. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternative rituximab.	
RxA.690.Rybrevant	1. Initial Approval Criteria, I.A.1: Updated indication from Diagnosis of advanced or metastatic NSCLC to Diagnosis of recurrent, advanced or metastatic NSCLC. 2. Initial Approval Criteria, I.A.5: Updated to remove subsequent therapy as a single agent for EGFR exon 20 insertion mutation positive recurrent, advanced, metastasis disease in patients with ECOG performance status 0-2. 3. Initial Approval Criteria I.A.6: Updated to remove member does not have untreated brain metastases and history of ILD requiring treatment with prolonged steroids or other immunosuppressive agents within the last 2 years. 4. Initial Approval Criteria, I.A.7.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). 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). 6. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. cisplatin b. carboplatin 7. Appendix D: Updated to remove information about ECOG performance score.	07.01.2023
RxA.694.Zynrelef	1. Initial Approval Criteria, I.A.1.c: Updated diagnostic criteria from Foot and ankle surgical procedures to Lower extremity total joint arthroplasty surgical procedures.	07.01.2023
RxA.696.Myfembree	1. Background: Updated to include new drug usage, management of moderate to severe pain associated with endometriosis. 2. Dosing Information, Indication: Updated to include new indication Moderate to severe pain associated with endometriosis. 3. Initial Approval Criteria, I.A.5: Updated to include new criteria pertaining to indication Heavy menstrual bleeding associated with uterine leiomyomas (fibroids), Member has not already received ≥ 24 cumulative months of Myfembree® therapy. 4. Initial Approval Duration for Heavy Menstrual Bleeding associated with Uterine Fibroids was updated from 6 months to 12 months. 5. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Moderate to severe pain associated with endometriosis.	07.01.2023

	6. Continued Therapy Approval Criteria, II.A.3: Updated to include new criteria pertaining to indication Heavy Menstrual Bleeding associated with Uterine Fibroids and Moderate to severe pain associated with endometriosis, Member has not already received ≥ 24 cumulative months of Myfembree® therapy. 7. Continued Approval Duration for both indications updated from 24 months to 12 months. 8. Added "*Total duration of therapy should not exceed 24 months"* verbiage after each approval duration section to reinforce 24-month utilization limit.	
RxA.712.Opzelura_Jakafi	1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Jakafi®. 2. Background: Updated to include new indication Jakafi® is a kinase inhibitor indicated for treatment of: • Intermediate or high-risk myelofibrosis (MF) in adults, including: ○ Primary MF ○ Post-polycythemia vera MF (post-PV MF) ○ Post-essential thrombocythemia MF (post-ET MF) • Polycythemia vera (PCV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. • Steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. • Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. 3. Dosing Information, Jakafi®: Updated to include Dosing information, Max dose, Hepatic and Renal impairment for indication MF, PCV, acute GVHD and cGVHD. 4. Dosage Forms, Jakafi®: Updated to include new dosage form, Tablets: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg. 5. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Myelofibrosis. 6. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Polycythemia Vera. 7. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Graft-Versus-Host Disease. 8. Initial Approval Criteria, I.F: Updated to include approval criteria for Off Label indication, Chronic Myelomonocytic Leukemia and Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN). 9. Initial Approval Criteria, I.G: Updated to include approval criteria for Off Label indication, Pediatric B-Cell Acute Lymphoblastic Leukemia.	07.01.2023

	10. Initial Approval Criteria, I.H: Updated to include approval criteria for Off Label indication, Myeloid/Lymphoid Neoplasm with Eosinophilia. 11. Initial Approval Criteria, I.I: Updated to include approval criteria for Off Label indication, Essential Thrombocythemia. 12. Initial Approval Criteria, I.J: Updated to include approval criteria for Off Label indication, CAR T-Cell Related Toxicities. 13. Continued Therapy Approval, II.C: Updated to include approval criteria for indication, Myelofibrosis, Polycythemia Vera and Graft-Versus-Host Disease. 14. Continued Therapy Approval, II.D: Updated to include approval criteria for indication, CAR T-cell-related toxicities. 15. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. hydroxyurea (Hydrea®), Droxia® b. Pegasys® c. anagrelide (Agrylin®) d. Systemic corticosteroids (e.g., methylprednisolone, prednisone) e. mycophenolate mofetil (Cellcept®) f. cyclosporine (Gengraf®, Neoral®, Sandimmune®) g. tacrolimus (Prograf®) h. sirolimus (Rapamune®) i. imatinib (Gleevec®) j. Imbruvica® k. Rezurock™ l. Actemra® m. dexamethasone n. methylprednisolone (Medrol®) 16. Appendix D, General Information: Updated to include new information regarding: a. Steroid Refractoriness or Resistance: Acute and Chronic GVHD (NCCN). b. CRS Grade (NCCN)	
RxA.723.Tezspire	1. Dosage Forms: Updated to include new dosage form, 210 mg/1.91 mL (110 mg/mL) solution in a single-dose pre-filled pen. 2. Initial Approval Criteria, I.A.4.a and I.A.4.b: Updated to remove prior trial and failure criteria "Failure of 3 month trial to high dose ICS plus other controller medication (a, b or c) with or without oral corticosteroids(OCO), at up to maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced: a. long-acting beta 2 agonist [LABA] inhaler; b. long-acting muscarinic antagonists [LAMA] inhaler; c. leukotriene modifier." 3. Initial Approval Criteria, I.A.5.a and I.A.5.b : Updated to remove prior diagnostic criteria "Member has experienced : (a or b);	07.01.2023

	a. Two or more asthma exacerbations requiring systemic corticosteroid treatment; b. One asthma exacerbation resulting in hospitalization in the past 12 months." 4. Initial Approval Criteria, I.A.4: Updated to include new criteria pertaining to indication Severe Asthma, Member has experienced ≥ 2 exacerbations with in the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid [ICS] plus either a long acting beta-2 agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance): a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid); b. Urgent care visit or hospital admission; c. Intubation. 5. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria Tezspire® is prescribed concurrently with an ICS plus either a LABA or LTRA. 6. Initial Approval Criteria, I.A.6: Updated combination therapy criteria from Member is not receiving Tezspire™ in combination with another biologic medication indicated for asthma treatment to Tezspire® is not prescribed concurrently with Cinqair®, Dupixent®, Fasenra®, Nucala®, or Xolair®. 7. Appendix A: Updated to include abbreviations LTRA and TSLP. 8. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. budesonide (Pulmicort™); b. Alvesco®; c. Arnuity Ellipta®; d. Asmanex®; e. Dulera®; f. fluticasone furoate/vilanterol trifenatate (Breo Ellipta®); g. fluticasone/ salmeterol (Advair®); h. fluticasone/salmeterol (Airduo RespiClick®); i. budesonide/ formoterol (Symbicort®); j. montelukast (Singulair®); k. zafirlukast (Accolate®); l. zileuton ER; m. zileuton (Zyflo®); n. methylprednisolone (Medrol®); o. prednisolone (Millipred®, Orapred ODT®); p. prednisone. 9. Appendix D, General Information: Updated to include new information regarding Phase 3 pivotal study for Tezspire.	

RxA.724.Vyvgart	1. Initial Approval Criteria, I.A.7: Updated to include new diagnostic criteria Vyvgart® is not prescribed concurrently with Soliris® or Ultomiris.	07.01.2023
RxA.725.Tarpeyo	1. Background: Updated information regarding accelerated approval This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo® slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. 2. Dosing Information, Dosing Regimen, budesonide (Tarpeyo®): Updated to include dosing information for discontinuing therapy for indication immunoglobulin A nephropathy. 3. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with a nephrologist. 4. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria Tarpeyo® is prescribed in combination with a RAS inhibitor. 5. Initial Approval Criteria, I.A.7: Updated from Member has eGFR ≥ 35 mL/min/1.73 m2 to Member has eGFR between or equal to 35 and 90 mL/min/1.73 m2. 6. Initial Approval Criteria, I.A.10: Updated to include new trial and failure criteria Trial and failure of two alternative systemic corticosteroids (e.g., methylprednisolone, prednisone), each used for at least 2 months, unless contraindicated or clinically significant adverse effects are experienced. 7. Initial Approval Criteria, I.A.11: Updated dosing criteria from Dose does not exceed 16 mg orally once daily to Dose does not exceed 16 mg orally once daily for 9 months, followed by 8 mg per day for two weeks. 8. Appendix B, Drug Name: Updated to include therapeutic alternative: a. methylprednisolone b. prednisone c. methylprednisolone (intravenous) + prednisolone/prednisone (oral)	07.01.2023
RxA.726.Humira_Amjevita	1. Clinical Policy Title: Updated from "adalimumab" to "adalimumab, adalimumab-atto" 2. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Amjevita™. 3. Background: Updated to include information regarding new drug Amjevita™. 4. Dosing Information, Drug Name: Updated to include new drug adalimumab-atto (Amjevita™). 5. Dosage Forms: Updated to include new brand dosage form, Single-dose prefilled SureClick® autoinjector: 40 mg/0.8 mL,	07.01.2023

	Single-dose prefilled glass syringe: 20 mg/0.4 mL, 40 mg/0.8 mL. 6. Initial Approval Criteria, I.B.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed one of the following (a, b or c): a. Only for Humira®: Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week; b. Weight 15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week; c. Weight ≥ 30 kg (66 lbs): 40 mg every other week. 7. Initial Approval Criteria, I.E.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed one of the following (a or b): a. Adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29; b. Pediatrics (i or ii): i. Weight 17 kg (37 lbs.) to < 40 kg (88 lbs.): 80 mg on Day 1 and 40 mg on Day 15, followed by maintenance dose of 20 mg every other week starting Day 29; ii. Weight ≥ 40 kg (88 lbs): 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29. 8. Initial Approval Criteria. I.F.3: Updated to include new age criteria For Amjevita™: Age ≥ 18 years. 9. Initial Approval Criteria, I.F.4: Updated to include new diagnostic criteria Documentation of a Mayo Score ≥ 6. 10. Initial Approval Criteria, I.F.6: Updated dosing criteria from Dose does not exceed (a or b): a. Age ≥ 18 years: 40 mg every other week; b. Age ≥ 6 years to 17 years: 80 mg every other week to Dose does not exceed one of the following (a, b or c): a. For adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29; b. For pediatric patients weighing more than 20 kg, but less than 40 kg: 80 mg on Day 1, 40 mg on Day 8 and Day 15, followed by maintenance doses of 40 mg every other week or 20 mg every week; c. For pediatric patients weighing more than 40 kg: 160 mg on Day 1 and 80 mg on Day 8 and 15, followed by maintenance doses of 80 mg every other week or 40 mg every week. 11. Initial Approval Criteria, I.G.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.	

	12. Initial Approval Criteria. I.H.2 and I.I.2: Updated to include new request criteria Request is for Humira. 13. Initial Approval Criteria, I.H.6: Updated dosing criteria from Dose does not exceed 40 mg/week to Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every week starting Day 29. 14. Initial Approval Criteria, I.I.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose. 15. For Amjevita™: All approval criteria updated to add that member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02). 16. Appendix B, Dosing Regimen, cyclophosphamide: Updated dosing information from 1 – 3 mg/kg/day orally to 1 – 3 mg/kg/day orally in combination with corticosteroids for indication Uveitis (off-label). 17. Appendix B, Dosing Regimen, mercaptopurine (Purixan®) : Updated dosing information from 50 mg orally once daily or 1– 2 mg/kg/day orally to 50 mg orally once daily or 1 – 1.5 mg/kg/day orally for indication Crohns disease Ulcerative colitis (off label) and Ulcerative colitis (off label). 18. Appendix B, Maximum Dose, mercaptopurine (Purixan®) : Updated maximum dose information from 2 mg/kg/day to 2.5 mg/kg/day for indication Crohns disease Ulcerative colitis (off label) and Ulcerative colitis (off label). 19. Appendix B, Dosing Regimen, Ilumya®: Updated dosing information from 100 mg subcutaneously at weeks 0 and 4 to 100 mg subcutaneously at weeks 0 and 4 and then every 12 weeks thereafter for indication Psoriasis. 20. Appendix D, General Information: Updated to include new information regarding mayo score which evaluates ulcerative colitis stage.	
RxA.727.Simponi_Simponi Aria	1. Initial Approval Criteria, 1.A.5.b: Updated dosing criteria for Simponi Aria® from dose does not exceed 2 mg/kg every 8 weeks to Simponi Aria® 2 mg/kg intravenously at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks. 2. Initial Approval Criteria, 1.B.4.b: Updated dosing criteria For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks to Simponi Aria® (i or ii): i. Adults: 2 mg/kg intravenously at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks; ii. Pediatrics: 80 mg/m2 intravenously at weeks 0 and 4, followed by maintenance dose of 80 mg/m2 every 8 weeks. 3. Initial Approval Criteria, 1.C.6.b: Updated dosing criteria for For Simponi Aria® dose does not exceed 2 mg/kg every 8 weeks to For Simponi Aria®: 2 mg/kg intravenously at	07.01.2023

	weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks. 4. Initial Approval Criteria, 1.D.7: Updated dosing criteria for Simponi® does not exceed 100 mg every 4 weeks to Dose does not exceed 200 mg at week 0, 100 mg at week 2, followed by maintenance dose of 100 mg every 4 weeks. 5. Initial Approval Criteria, I.D.5: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 6. Initial Approval Criteria, 1.E.6: Updated dosing criteria for Simponi® Dose does not exceed 80 mg/m2 every 8 weeks to Dose does not exceed 80 mg/m2 intravenously at weeks 0 and 4, followed by maintenance dose of 80 mg/m2 every 8 weeks. 7. Appendix B, Drug Name: Updated to include generic therapeutic alternative infliximab (Remicade®). 8. Appendix D, General Information: Updated to include information regarding Mayo score.	
RxA.729.Tremfya	No updates	07.01.2023
RxA.730.Actemra	1. Background: Updated to include new indication coronavirus disease 2019 (COVID-19). 2. Dosing Information, Indication: Updated to include new indication coronavirus disease 2019 (COVID-19). 3. Initial Approval Criteria I.A, I.C: Updated to add Amjevita™ as one of trial and failure criteria alternative drug. 4. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, Coronavirus Disease 2019 (COVID-19). 5. Continued Therapy Approval Criteria II.B.: Updated to include approval criteria for indication, Coronavirus Disease 2019 (COVID-19). 6. Appendix B, Dosing Regimen, methotrexate: Updated dosing information from 7.5 mg/week orally, subcutaneous, or intramuscular or 2.5 mg orally every 12 hr for 3 doses/week to 7.5 to 15 mg orally or subcutaneously once weekly, initially. Increase the dose to at least 15 mg/week to achieve optimal response. 7. Appendix B, Maximum Dose, methotrexate: Updated maximum dose information from 30 mg/week to 20 to 30 mg/m2/week (0.65 to 1 mg/kg/week) is a usual maximum dose for indication polyarticular juvenile idiopathic arthritis. 8. Appendix B, Maximum Dose, methotrexate: Updated maximum dose information from 30 mg/week to 20 mg/week for indication RA.	07.01.2023
RxA.731.Avsola	1. Initial Approval Criteria, I.A.5, I.B.5. I.C.5, I.D.4 and I.F.6: Updated dosing criteria from Dose does not exceed 5 mg/kg every 8 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks.	07.01.2023

	2. Initial Approval Criteria, I.C.1: Updated diagnosis criteria from Diagnosis of PsO to Diagnosis of chronic-severe PsO as evidenced by involvement of one of the following (a or b): a. ≥ 10% of total body surface area; b. Hands, feet, scalp, face, or genital area 3. Initial Approval Criteria, I.E.6: Updated dosing criteria from Dose does not exceed 10 mg/kg every 8 weeks to Dose does not exceed 3 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 3 mg/kg every 8 weeks. 4. Initial Approval Criteria, I.F.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 5. Appendix D, General Information: Updated to include information regarding Mayo score.	
RxA.732.Cimzia	1. Initial Approval Criteria, I.A.5, I.B.5, I.D.4 and I.E.5: Updated dosing criteria from Dose does not exceed 400 mg every 4 weeks to Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks. 2. Initial Approval Criteria, I.C.1: Updated diagnosis criteria from Diagnosis of PsO to Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b): a. ≥ 3% of total body surface area; b. Hands, feet, scalp, face, or genital area 3. Initial Approval Criteria, I.E.5: Updated dosing criteria from Dose does not exceed 400 mg every 4 weeks to Dose does not exceed 400 mg every 2 weeks. 4. Continued Therapy Approval. II.A.3: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 400 mg every 4 weeks to If request is for a dose increase, new dose does not exceed (a or b): a. For CD, RA, PsA, AS, nr-axSpA: 400 mg every 4 weeks; b. For PsO: 400 mg every 2 weeks	07.01.2023
RxA.733.Cosentyx	1. Initial Approval Criteria, I.A.5.a, I.B.5.a and I.C.4.a: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.735.Entyvio	1. Initial Approval Criteria, I.A.6 and I.B.7: Updated dosing criteria from Dose does not exceed 300 mg per dose to Dose does not exceed 300 mg at weeks 0, 2, and 6, followed by maintenance dose of 300 mg every 8 weeks. 2. Initial Approval Criteria, I.B.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 3. Initial Approval Criteria I.A.5: Updated to add Amjevita™ and Syrizi ® as trial and failure options. 4. Initial Approval Criteria I.B.6: Updated to add Amjevita™, Rinvoq®, Xeljanz®/XR as trial and failure options. 5. Appendix A: Updated to include abbreviations FDA. 6. Appendix B, Dosing Regimen, sulfasalazine (Azulfidine®):	07.01.2023

	Updated to include dosing information for indication CD (off-label). 7. Appendix B, Maximum Dose, sulfasalazine (Azulfidine®): Updated to include maximum dose information for indication CD (off-label). 8. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. Amjevita™; b. Zeposia®. 9. Appendix D, General Information: Updated to include information regarding Mayo score.	
RxA.736.Ilumya	1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.737.Inflectra	1. Initial Approval Criteria, I.A.5: Updated dosing criteria from Dose does not exceed 5 mg/kg every 6 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 6 weeks. 2. Initial Approval Criteria, I.C.1: Updated diagnostic criteria from Diagnosis of Plaque Psoriasis (PsO) to Diagnosis of chronic-severe Plaque Psoriasis (PsO) as evidenced by involvement of one of the following (a or b): a. ≥ 10% of total body surface area; b. Hands, feet, scalp, face, or genital area; 3. Initial Approval Criteria, I.B.5, I.C.5; I.D.4 and I.F.5: Updated dosing criteria from Dose does not exceed 5 mg/kg every 8 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks. 4. Initial Approval Criteria, I.E.6: Updated dosing criteria from Dose does not exceed 10 mg/kg every 4 weeks to Dose does not exceed 3 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 3 mg/kg every 8 weeks. 5. Initial Approval Criteria, I.F.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 6. Appendix B, Dosing Regimen, tacrolimus (Prograf®): Updated to include dosing information for indication Pso (off-label). 7. Appendix D, General Information: Updated to include information regarding Mayo score.	07.01.2023
RxA.738.Kevzara	1. Background: Updated to include new indication polymyalgia rheumatica (PMR). 2. Dosing Information, Indication: Updated to include new indication PMR. 3. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™. 4. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Polymyalgia rheumatica (PMR).	07.01.2023

	5. Continued Therapy Approval Criteria, II.A: Updated to include approval criteria for indication, Polymyalgia rheumatica (PMR).	
RxA.739.Kineret	1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.740.Olumiant	1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.741.Orencia	1. Initial Approval Criteria, I.A.5, I.B.4 and I.C.5: Updated trial and failure criteria to include new preferred brand, Amjevita™.	07.01.2023
RxA.742.Otezla	No updates	07.01.2023
RxA.743.Remicade	1. Initial Approval Criteria, I.A.6: Updated dosing criteria from Dose does not exceed 5 mg/kg every 6 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 6 weeks. 2. Initial Approval Criteria, I.B.6: Updated dosing criteria from Dose does not exceed one of the following: (a or b) a. Age ≥ 18 years: 10 mg/kg every 8 weeks; b. Age ≥ 6 years but < 18 years: 5 mg/kg every 8 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks. 3. Initial Approval Criteria, I.C.1: Updated diagnostic criteria from Diagnosis of Plaque Psoriasis (PsO) to Diagnosis of chronic-severe Plaque Psoriasis (PsO) as evidenced by involvement of one of the following (a or b): a. ≥ 10% of total body surface area; b. Hands, feet, scalp, face, or genital area; 4. Initial Approval Criteria, I.C.6: Updated dosing criteria from Dose does not exceed 5 mg/kg every 8 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks. 5. Initial Approval Criteria, I.D.6: Updated dosing criteria from Dose does not exceed 5 mg/kg every 8 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks. 6. Initial Approval Criteria, I.E.5: Updated to include new combination therapy criteria, Prescribed concomitantly with MTX, or another DMARD if intolerance or contraindication to MTX. 7. Initial Approval Criteria, I.E.6: Updated dosing criteria from Dose does not exceed 10 mg/kg every 4 weeks to Dose does not exceed 3 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 3 mg/kg every 8 weeks. 8. Initial Approval Criteria, I.F.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 9. Initial Approval Criteria, I.F.6: Updated dosing criteria from Dose does not exceed 5 mg/kg every 8 weeks to Dose does	07.01.2023

	not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks. 10. Appendix D, General Information: Updated to include information regarding Mayo score.	
RxA.744.Renflexis	1. Initial Approval Criteria, I.A.5, I.B.7 and I.C.7: Updated dosing criteria from Dose does not exceed 5 mg/kg every 8 weeks to Dose does not exceed 5 mg/kg at weeks 0, 2, and 6, followed by maintenance dose of 5 mg/kg every 8 weeks. 2. Initial Approval Criteria, I.B.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 3. Initial Approval Criteria, I.F.1: Updated diagnosis criteria from Diagnosis of PsO to Diagnosis of chronic-severe PsO as evidenced by involvement of one of the following (a or b): a. ≥ 10% of total body surface area; b. Hands, feet, scalp, face, or genital area 4. Appendix D, General Information: Updated to include information regarding Mayo score.	07.01.2023
RxA.746.Siliq	1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.748.Taltz	1. Initial Approval Criteria, I.A.5.a, I.B.5 and I.C.4: Updated trial and failure criteria to include new drug Amjevita™.	07.01.2023
RxA.750.Recorlev	1. Initial Approval Criteria I.A.6: Updated to remove requirement for documentation of baseline urinary free cortisol and baseline liver enzyme function tests; 2. Appendix B, Dosing Regimen, mitotane: Updated to include dosing information for indication cushing syndrome. 3. Appendix D: Updated to add information about ketoconazole use for the treatment of CS.	07.01.2023
RxA.751.Tascenso_ODT	1. Background: Updated to remove detail pertaining to indication MS, "and weighing less than or equal to 40 kg." 2. Dosing Information, Dosing Regimen, Tascenso ODT™: Updated to include dosing information for weights > 40 kg for indication MS. 3. Dosage Forms: Updated to include new dosage form, 0.5 mg. 4. Initial Approval Criteria, I.A.5: Updated to remove dosage form 0.25 mg. 5. Initial Approval Criteria, I.A.8: Updated dosing criteria from Dose does not exceed 0.25 mg orally once daily to Dose does not exceed one of the following (a or b): a. Adults and pediatric weighing > 40 kg: 0.5 mg per day; b. Pediatric weighing ≤ 40 kg: 0.25 mg per day. 6. Continued Therapy Approval, II.A.4: Updated dosing criteria from If request is for dose increase, new dose does not exceed 0.25 mg orally once daily to If request is for dose increase, new dose does not exceed one of the following (a or b): a. Adults and pediatric weighing > 40 kg: 0.5 mg per day;	07.01.2023

	b. Pediatric weighing ≤ 40 kg: 0.25 mg per day.	
RxA.752.Cibinqo	1. Background: Updated information regarding age limit from adult to adults and pediatric patients 12 years of age and older. 2. Initial Approval Criteria, I. A.2: Updated age criteria from Age ≥18 years to Age ≥12 years;	07.01.2023
RxA.753.Enjaymo	1. Clinical Policy Title: Updated from "sutimlimab" to "sutimlimab-jome". 2. Background: Updated indication from Enjaymo™ (sutimlimab-jome) is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD) to Enjaymo™ (sutimlimab-jome) is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD). 3. Initial Approval Criteria I.A.7: Updated to add Enjaymo™ is not prescribed concurrently with rituximab or rituximab-based regimens (i.e., rituximab with bendamustine or fludarabine). 4. Initial Approval Criteria I.A.7:Updated to remove criteria presence of one or more symptoms associated with CAD.	07.01.2023
RxA.754.Kimmtrak	1. Initial Approval Criteria, I.A.8.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). 2. Initial Approval Criteria I.A.6: Updated to remove Member does not have prior regional, liver-directed therapy including chemotherapy, radiotherapy, or embolization. 3. Initial Approval Criteria I.A.7: Updated to remove Member has Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. 4. Continued Therapy Approval Criteria, II.A.3.b new dosing criteria Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). 5. Continued Therapy Approval: Approval duration updated from 6 months to 12 months.	07.01.2023
RxA.755.Pyrukynd	1. Dosing Information, Dosing Regimen, mitapivat (Pyrukynd®): Updated to include Dose may be increased every 4 weeks based on response and tolerance to 20 mg twice daily up to a maximum of 50 mg twice daily 2. Initial Approval Criteria I.A.9: Updated to add prescribed concurrently with oral folic acid.	07.01.2023
RxA.756.Vonjo	1. Initial Approval Criteria 1.A.4: Platelet count of ≥ 50 x 109/L updated to > 50 x 109/L. 2. Continued Therapy Criteria: Approval duration updated from 6 months to 12 months.	07.01.2023
RxA.757.Eysuvis	1. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria Trial and failure of at least one other	07.01.2023

	ophthalmic anti-inflammatory agent (see Appendix B for examples) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced. 2. Appendix B, Drug Name: Updated to include new therapeutic alternative ophthalmic anti-inflammatory agents for dry eye disease (e.g., loteprednol etabonate 0.2%, 0.5%).	
RxA.758.Bebtelovimab	1. Initial Approval Criteria I.A.2: Updated to add member is within 7 days of symptom onset. 2. Initial Approval Criteria I.A.3: Updated to add Bebtelovimab will be administered as a single intravenous injection. 3. Initial Approval Criteria: Approval duration updated from 7 days to one time.	07.01.2023
RxA.759.Entadfi	1. Initial Approval Criteria I.A.3: Updated to add alpha-blockers as one of trial and failure options. 2. Initial Approval Criteria I.A.4: Updated to add Medical justification as to why individual agents cannot be given.	07.01.2023
RxA.778.Imjudo	1. Initial Approval Criteria, I.A: Updated approval duration from “One lifetime dose only” to “6 months” for Commercial and Medicaid.	07.01.2023
RxA.805.Sotyktu	1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria from at least 3 to at least 2 agents and also include new drug Amjevita™.	07.01.2023

New Step Therapy

- Mydayis 12.5 mg capsule extended release 24 hr, Mydayis 25 mg capsule extended release 24 hr, Mydayis 37.5 mg capsule extended release 24 hr, Mydayis 50 mg capsule extended release 24 hr.
- Dextroamphetamine-amphetamine 12.5 mg tablet, Dextroamphetamine-amphetamine 10 mg tablet, Dextroamphetamine-amphetamine 5 mg tablet, Dextroamphetamine-amphetamine 20 mg tablet, Dextroamphetamine-amphetamine 15 mg tablet, Dextroamphetamine-amphetamine 30 mg tablet, Dextroamphetamine-amphetamine 7.5 mg tablet.
- Dexmethylphenidate 5 mg tablet, Dexmethylphenidate 10 mg tablet, Dexmethylphenidate 2.5 mg tablet
- Dexmethylphenidate ER 30 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 15 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 10 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 5 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 35 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 20 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 40 mg capsule, extended release biphasic 50-50, Dexmethylphenidate ER 25 mg capsule, extended release biphasic 50-50.
- Dextroamphetamine sulfate ER 5 mg capsule, extended release, Dextroamphetamine sulfate ER 15 mg capsule, extended release, Dextroamphetamine sulfate ER 10 mg capsule, extended release.
- Dextroamphetamine sulfate 10 mg tablet, Dextroamphetamine sulfate 5 mg tablet, Dextroamphetamine sulfate 15 mg tablet, Dextroamphetamine sulfate 20 mg tablet, Dextroamphetamine sulfate 30 mg tablet.
- Dextroamphetamine sulfate 5 mg/5 mL oral solution.
- Methylphenidate 5 mg tablet, Methylphenidate 20 mg tablet, Methylphenidate 10 mg tablet.
- Methylphenidate 2.5 mg chewable tablet, Methylphenidate 10 mg chewable tablet.
- Methylphenidate 5 mg/5 mL oral solution, Methylphenidate 10 mg/5 mL oral solution.
- Methylphenidate ER 10 mg tablet, extended release, Methylphenidate ER 20 mg tablet, extended release.

- Methylphenidate CD 10 mg biphasic 30-70 capsule, extended release, Methylphenidate CD 20 mg biphasic 30-70 capsule, extended release, Methylphenidate CD 30 mg biphasic 30-70 capsule, extended release, Methylphenidate CD 40 mg biphasic 30-70 capsule, extended release, Methylphenidate CD 50 mg biphasic 30-70 capsule, extended release, Methylphenidate CD 60 mg biphasic 30-70 capsule, extended release.
- Methylphenidate LA 10 mg biphasic 50-50 capsule, extended release, Methylphenidate LA 20 mg biphasic 50-50 capsule, extended release, Methylphenidate LA 30 mg biphasic 50-50 capsule, extended release, Methylphenidate LA 40 mg biphasic 50-50 capsule, extended release, Methylphenidate LA 60 mg biphasic 50-50 capsule, extended release.
- Methylphenidate ER 10 mg capsule, extended release (40-60) sprinkle, Methylphenidate ER 15 mg capsule, extended release (40-60) sprinkle, Methylphenidate ER 20 mg capsule, extended release (40-60) sprinkle, Methylphenidate ER 30 mg capsule, extended release (40-60) sprinkle, Methylphenidate ER 40 mg capsule, extended release (40-60) sprinkle, Methylphenidate ER 50 mg capsule, extended release (40-60) sprinkle, Methylphenidate ER 60 mg capsule, extended release (40-60) sprinkle.
- Methylphenidate ER 18 mg tablet, extended release 24 hr, Methylphenidate ER 27 mg tablet, extended release 24 hr, Methylphenidate ER 36 mg tablet, extended release 24 hr, Methylphenidate ER 45 mg tablet, extended release 24 hr, Methylphenidate ER 54 mg tablet, extended release 24 hr, Methylphenidate ER 63 mg tablet, extended release 24 hr, Methylphenidate ER 72 mg tablet, extended release 24 hr.
- Vyvanse 20 mg capsule, Vyvanse 30 mg capsule, Vyvanse 40 mg capsule, Vyvanse 10 mg capsule, Vyvanse 70 mg capsule, Vyvanse 50 mg capsule, Vyvanse 60 mg capsule.
- Vyvanse 60 mg chewable tablet, Vyvanse 20 mg chewable tablet, Vyvanse 50 mg chewable tablet, Vyvanse 40 mg chewable tablet, Vyvanse 10 mg chewable tablet, Vyvanse 30 mg chewable tablet.
- Azstarys 39.2 mg-7.8 mg capsule, Azstarys 52.3 mg-10.4 mg capsule, Azstarys 26.1 mg-5.2 mg capsule.
- Jornay PM 100 mg capsule, delayed release, extended release sprinkle; Jornay PM 20 mg capsule, delayed release, extended release sprinkle, Jornay PM 80 mg capsule, delayed release, extended release sprinkle, Jornay PM 60 mg capsule, delayed release, extended release sprinkle, Jornay PM 40 mg capsule, delayed release, extended release sprinkle.

Updated Step Therapy

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