Third Quarter 2021 Drug Formulary and Clinical Updates

Date of Notice: 12/01/2021

Formulary Updates

Drug Name, Strength(s), & Dosage Form(s)	Description of Change	Formulary Status	Alternative Drug(s) (if applicable)	Effective Date
Brexafemme 150 mg tablet (New Drug)	Formulary Addition; PA Addition; QL Addition	Non-Preferred Brand		12/01/21
Bylvay 1,200 mcg capsule (New Drug), Bylvay 200 mcg capsule (New Drug), Bylvay 400 mcg capsule (New Drug), Bylvay 600 mcg capsule (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		12/01/21
Empaveli 1,080 mg/20 ml subcutaneous solution (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		12/01/21
Kerendia 10 mg tablet (New Drug), Kerendia 20 mg tablet (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		12/01/21
Lumakras 120 mg tablet (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		12/01/21
Myfembree 40-1-0.5 mg tablet (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		12/01/21
Rezurock 200 mg tablet (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		12/01/21
Rybrevant 50 mg/ml IV solution (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		12/01/21
Rylaze 10 mg/0.5 ml IM solution (New Drug)	Formulary Addition; PA Addition; Specialty Addition	Preferred Brand		12/01/21
Saphnelo 300 mg/2 ml (150 mg/ml) IV solution (New Drug)	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		12/01/21
Truseltiq 100 mg/day (100 mg x 1) capsule (New Drug), Truseltiq 125 mg/day (100 mg x1-25mg x1) capsule (New Drug), Truseltiq 50 mg/day (25 mg x 2) capsule (New Drug),	Formulary Addition; PA Addition; QL Addition; Specialty Addition	Non-Preferred Brand		12/01/21

Truseltiq 75 mg/day (25 mg x 3) capsule (New Drug)				
Zynrelef 200 mg-6 mg /7 ml implantation solution ER (New Drug), Zynrelef 400 mg-12 mg /14 ml implantation solution ER (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		12/01/21
Camcevi 42 mg injectable emulsion (New Drug)	Formulary Addition; PA Addition; QL Addition; SPS Addition	Non-Preferred Brand		12/01/21
Lybalvi 5 mg/10 mg tablet (New Drug), Lybalvi 10 mg/10 mg tablet (New Drug), Lybalvi 15 mg/10 mg tablet (New Drug), Lybalvi 20 mg/10 mg tablet (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		12/01/21
Twyneo 0.1%/3% cream (New Drug)	Formulary Addition; PA Addition	Non-Preferred Brand		12/01/21
Movantik 12.5 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Adzenys ER 1.25 mg/mL suspension, ER 24 hr	QL Addition	Non-Preferred Brand		12/01/21
Amphetamine ER 1.25 mg/mL 24 hr ER suspension	QL Addition	Generic		12/01/21
Zenzedi 10 mg tablet	QL Update	Non-Preferred Brand		12/01/21
Zenzedi 15 mg tablet, Zenzedi 2.5 mg tablet, Zenzedi 20 mg tablet, Zenzedi 30 mg tablet, Zenzedi 5 mg tablet, Zenzedi 7.5 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Dexedrine spansule 5 mg capsule ER	QL Update	Non-Preferred Brand		12/01/21
Dextroamphetamine 5 mg tablet, Dextroamphetamine ER 5 mg capsule	QL Update	Generic		12/01/21
Pilocarpine 7.5 mg tablet	QL Addition	Generic		12/01/21

Salagen 7.5 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Amphetamine sulfate 10 mg tablet, Amphetamine sulfate 5 mg tablet	QL Addition	Generic		12/01/21
Dextroamphetamine 5 mg/5 mL solution	QL Addition	Generic		12/01/21
Procentra 5 mg/5 mL solution	QL Addition	Non-Preferred Brand		12/01/21
Afirmelle 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Altavera (28) 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Alyacen 1/35 (28) 1-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Amethyst (28) 90 mcg-20 mcg tablet	QL Addition	Preventive Medications		12/01/21
Apri 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Lutera (28) 0.5/1/0.5-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Aubra 0.1-20 mg-mcg tablet, Aubra eq 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Aurovela 1.5/30 (21) 1.5-30 mg-mcg tablet, Aurovela 1/20 (21) 1 mg-20 mcg tablet, Aurovela 24 Fe 1 mg-20 mcg (24)/75 mg (4) tablet, Aurovela Fe 1.5/30 (28) 1.5 mg-30 mcg (21)/75 mg (7) tablet, Aurovela Fe 1-20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet	QL Addition	Preventive Medications		12/01/21
Ayuna 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Azurette (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Balziva (28) 0.4-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21

Bekyree (28) 0.15-0.02 mg x 21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Blisovi 24 Fe 1 mg-20 mcg (24)/75 mg (4) tablet, Blisovi Fe 1.5/30 (28) 1.5 mg-30 mcg (21)/75 mg (7) tablet, Blisovi Fe 1/20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet	QL Addition	Preventive Medications		12/01/21
Briellyn 0.4-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Caziant (28) 0.1/.125/.15-25 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Charlotte 24 Fe 1 mg-20 mcg (24) /75 mg (4) tablet, chewable	QL Addition	Preventive Medications		12/01/21
Chateal (28) 0.15 mg-0.03 mg tablet, Chateal eq (28) 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Cryselle (28) 0.3-30 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Cyclafem 1/35 (28) 1-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Cyred 0.15-0.03 mg tablet, Cyred eq 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Dasetta 1/35 (28) 1-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Desog-e.estradiol/e.estradiol 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Elinest 0.3 mg-30 mcg tablet	QL Addition	Preventive Medications		12/01/21
Eluryng 0.12 mg-0.015 mg/24 hr vaginal ring	QL Addition	Preventive Medications		12/01/21
Enpresse 50-30 (6)/75-40 (5)/125-30(10) tablet	QL Addition	Preventive Medications		12/01/21
Enskyce 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Estrostep Fe-28 1-20(5)/1-30(7) /1mg-35mcg (9) tablet	QL Addition	Non-Preferred Brand		12/01/21
Ethynodiol diac-eth estradiol 1-35 mg-mcg tablet,	QL Addition	Preventive Medications		12/01/21

Ethynodiol diac-eth estradiol 1-50 mg-mcg tablet				
Etonogestrel 0.12 mg-ethinyl estradiol 0.015 mg/24 hr vaginal ring	QL Update	Preventive Medications		12/01/21
Falmina (28) 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Hailey 1.5 mg-30 mcg tablet, Hailey 24 Fe 1 mg-20 mcg (24)/75 mg (4) tablet, Hailey Fe 1.5/30 (28) 1.5 mg-30 mcg (21)/75 mg (7) tablet, Hailey Fe 1/20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet	QL Addition	Preventive Medications		12/01/21
Iclevia 0.15 mg-30 mcg (91) tablet, dose pack, 3 months	QL Addition	Preventive Medications		12/01/21
Isibloom 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Jaimiess 0.15 mg-30 mcg (84)/10 mcg (7) tablet, dose pack, 3 months	QL Addition	Preventive Medications		12/01/21
Juleber 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Junel 1.5/30 (21) 1.5 mg-30 mcg tablet, Junel 1/20 (21) 1 mg-20 mcg tablet, Junel Fe 1.5/30 (28) 1.5 mg-30 mcg (21)/75 mg (7) tablet, Junel Fe 1/20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet, Junel Fe 24 1 mg-20 mcg (24)/75 mg (4) tablet	QL Addition	Preventive Medications		12/01/21
Kalliga 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Kariva (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Kelnor 1/35 (28) 1-35 mg-mcg tablet, Kelnor 1-50 (28) 1-50 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Kurvelo (28) 0.15 mg-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21

Larin 1.5/30 (21) 1.5 mg-30 mcg tablet, Larin 1/20 (21) 1 mg-20 mcg tablet, Larin 24 Fe 1 mg-20 mcg (24)/75 mg (4) tablet, Larin Fe 1.5/30 (28) 1.5 mg-30 mcg (21)/75 mg (7) tablet, Larin Fe 1/20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet	QL Addition	Preventive Medications		12/01/21
Larissia 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Leena 28 0.5/1/0.5-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Lessina 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Levonest (28) 50-30 (6)/75-40(5)/125-30(10) tablet	QL Addition	Preventive Medications		12/01/21
Levonorgestrel-ethinyl estrad 0.1-20 mg-mcg tablet, Levonorgestrel-ethinyl estrad 0.15-0.03 mg tablet, Levonorgestrel-ethinyl estradiol 90 mcg-20 mcg (28) tablet	QL Addition	Preventive Medications		12/01/21
Levonorg-eth estrad triphasic 50-30 (6)/75-40 (5)/125-30(10) tablet	QL Addition	Preventive Medications		12/01/21
Levora-28 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Lillow (28) 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Loestrin 1.5/30 (21) 1.5 mg-30 mcg tablet, Loestrin 1/20 (21) 1 mg-20 mcg tablet, Loestrin Fe 1.5/30 (28-day) 1.5 mg-30 mcg (21)/75 mg (7) tablet, Loestrin Fe 1/20 (28-day) 1 mg-20 mcg (21)/75 mg (7) tablet	QL Addition	Preventive Medications		12/01/21
Lojaimiess 0.10 mg-20 mcg (84)/10 mcg (7) tablet, dose pack, 3 months	QL Addition	Preventive Medications		12/01/21
Low-ogestrel (28) 0.3-30 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21

Lutera (28) 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Lyleq 0.35 mg tablet	QL Addition	Preventive Medications		12/01/21
Marlissa (28) 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Merzee 1 mg-20 mcg (24)/75 mg (4) capsule	QL Addition	Preventive Medications		12/01/21
Microgestin 1.5/30 (21) 1.5 mg-30 mcg tablet, Microgestin 24 Fe 1 mg-20 mcg (24)/75 mg (4) tablet, Microgestin Fe 1.5/30 (28) 1.5 mg-30 mcg (21)/75 mg (7) tablet	QL Addition	Non-Preferred Brand		12/01/21
Microgestin Fe 1/20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet, Microgestin 1/20 (21) 1 mg-20 mcg tablet	QL Addition	Preventive Medications		12/01/21
Mircette (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Necon 0.5/35 (28) 0.5-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Noreth-ethinyl estradiol-iron 0.4mg-35mcg (21) and 75 mg (7) tablet,chewable	QL Addition	Preventive Medications		12/01/21
Norethindrone acetate 1 mg-ethinyl estradiol 20 mcg tablet, Norethindrone acetate 1.5 mg-ethinyl estradiol 30 mcg tablet, Norethindrone-e.estradiol-iron 1 mg-20 mcg (21)/75 mg (7) tablet, Norethindrone-e.estradiol-iron 1.5 mg-30 mcg (21)/75 mg (7) tablet, Norethindrone-e.estradiol-iron 1 mg-20 mcg (24)/75 mg (4) capsule	QL Addition	Preventive Medications		12/01/21
Nortrel 0.5/35 (28) 0.5-35 mg-mcg tablet, Nortrel 1/35 (21) 1 mg-35 mcg tablet, Nortrel 1/35 (28) 1 mg-35 mcg tablet	QL Addition	Preventive Medications		12/01/21
Nuvaring 0.12 mg-0.015 mg/24 hr vaginal ring	QL Update	Non-Preferred Brand		12/01/21

Nymyo 0.25-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Orsythia 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Philith 0.4-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Pimtrea (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Pirmella 1-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Portia 28 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Reclipsen (28) 0.15-0.03 mg tablet	QL Addition	Preventive Medications		12/01/21
Simliya (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Slynd 4 mg (28) tablet	QL Addition	Preventive Medications		12/01/21
Sronyx 0.1-20 mg-mcg tablet	QL Update	Preventive Medications		12/01/21
Tarina Fe 1/20 (28) 1 mg-20 mcg (21)/75 mg (7) tablet, Tarina Fe 1-20 eq (28) 1 mg-20 mcg (21)/75 mg (7) tablet, Tarina 24 fe 1 mg-20 mcg (24)/75 mg (4) tablet	QL Addition	Preventive Medications		12/01/21
Taytulla 1 mg-20 mcg (24)/75 mg (4) capsule	QL Addition	Preventive Medications		12/01/21
Tilia Fe 1-20(5)/1-30(7) /1mg-35mcg (9) tablet	QL Addition	Preventive Medications		12/01/21
Tri-legest Fe 1-20(5)/1-30(7) /1mg-35mcg (9) tablet	QL Addition	Preventive Medications		12/01/21
Trivora (28) 50-30 (6)/75-40 (5)/125-30(10) tablet	QL Addition	Preventive Medications		12/01/21
Tyblume 0.1 mg- 20 mcg chewable tablet	QL Addition	Preventive Medications		12/01/21
Velivet triphasic regimen (28) 0.1/.125/.15-25 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21

Vienva 0.1-20 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Viorele (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Volnea (28) 0.15-0.02 mgx21 /0.01 mg x 5 tablet	QL Addition	Preventive Medications		12/01/21
Vyfemla (28) 0.4-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Wera (28) 0.5 mg-35 mcg tablet	QL Update	Preventive Medications		12/01/21
Wymzya Fe 0.4 mg-35 mcg (21)/75 mg (7) chewable tablet	QL Addition	Preventive Medications		12/01/21
Zovia 1/35e (28) 1-35 mg-mcg tablet	QL Addition	Preventive Medications		12/01/21
Xulane 150 mcg-35 mcg/24 hr transdermal patch	QL Addition	Preventive Medications		12/01/21
Azelastine-fluticasone 137-50 mcg/spray nasal aerosol, spray with pump (gram)	QL Addition	Generic		12/01/21
Latanoprost (PF) 0.005 % ophthalmic (eye) drops	Formulary Deletion	Non-Formulary	Latanoprost 0.005% ophthalmic drops; Dorzolamide-timolol (PF) 2-0.5% ophthalmic drops, Dorzolamide-timolol (PF) 2-0.5% ophthalmic single-use dropperette; Timolol maleate (PF) 0.5% ophthalmic single-use dropperette	12/01/21
Xiidra 5 % ophthalmic (eye) dropperette, single-use drop dispenser	Formulary Update; QL Addition; PA Deletion	Preferred Brand		12/01/21
Restasis 0.05 % ophthalmic (eye) dropperette, single-use drop dispenser	QL Update	Preferred Brand		12/01/21

Ddavp 0.1 mg/mL (refrigerate) nasal solution	QL Addition	Preferred Brand		12/01/21
Ddavp 0.1 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Ddavp 0.2 mg tablet	QL Update	Non-Preferred Brand		12/01/21
Desmopressin 0.1 mg tablet, Desmopressin 10 mcg/spray (0.1 mL) nasal aerosol, spray with pump (ml)	QL Addition	Generic		12/01/21
Desmopressin 0.2 mg tablet	QL Update	Generic		12/01/21
Makena 250 mg/mL (1 mL) IM (ml), Makena 250 mg/mL IM (ml)	QL Addition	Non-Preferred Brand		12/01/21
Medroxyprogesterone 2.5 mg tablet, Medroxyprogesterone 5 mg tablet	QL Addition	Generic		12/01/21
Oxandrin 2.5 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Oxandrolone 2.5 mg tablet	QL Addition	Generic		12/01/21
Premarin 0.9 mg tablet	QL Addition	Preferred Brand		12/01/21
Provera 5 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Bupropion HCl (smoking deter) 150 mg tablet, ER 12 hr, Bupropion HCl 100 mg tablet, Bupropion HCl SR 100 mg tablet, Bupropion HCl SR 150 mg tablet, Bupropion HCl SR 200 mg tablet, Bupropion HCl SR 75 mg tablet	QL Addition	Generic		12/01/21
Chantix 0.5 mg tablet, Chantix starting month box 0.5 mg (11)- 1 mg (42) tablet, dose pack	QL Addition	Non-Preferred Brand		12/01/21
Varenicline 0.5 mg tablet	QL Addition	Generic		12/01/21
Cytomel 25 mcg tablet, Cytomel 50 mcg tablet	QL Deletion	Non-Preferred Brand		12/01/21
Euthyrox 112 mcg tablet, Euthyrox 125 mcg tablet,	QL Deletion	Non-Preferred Brand		12/01/21

Euthyrox 175 mcg tablet, Euthyrox 200 mcg tablet				
Aripiprazole 10 mg tablet, Aripiprazole 2 mg tablet, Aripiprazole 30 mg tablet, Aripiprazole 5 mg tablet, Aripiprazole 10 mg disintegrating tablet, Aripiprazole 15 mg disintegrating tablet, Aripiprazole 1 mg/mL solution	QL Addition	Generic		12/01/21
Duloxetine 40 mg DR capsule	QL Addition	Generic		12/01/21
Effexor XR 150 mg capsule ER	QL Update	Non-Preferred Brand		12/01/21
Escitalopram 20 mg tablet	QL Addition	Generic		12/01/21
Escitalopram oxalate 10 mg tablet, Escitalopram oxalate 5 mg tablet, Escitalopram oxalate 5 mg/5 mL solution	QL Addition	Generic		12/01/21
Fetzima 20 mg (2)- 40 mg (26) capsule, ER 24 hr dose pack	QL Addition	Non-Preferred Brand		12/01/21
Fluoxetine 10 mg capsule, Fluoxetine 20 mg capsule, Fluoxetine 10 mg tablet, Fluoxetine 90 mg capsule DR	QL Addition	Generic		12/01/21
Fluoxetine 20 mg/5 mL (4 mg/mL) solution	QL Update	Generic		12/01/21
Fluvoxamine 150 mg capsule, ER 24 hr, Fluvoxamine 25 mg tablet, Fluvoxamine 50 mg tablet	QL Addition	Generic		12/01/21
Lithium carbonate 300 mg capsule	QL Deletion	Generic		12/01/21
Prozac 20 mg capsule	QL Addition	Non-Preferred Brand		12/01/21
Rexulti 0.25 mg tablet, Rexulti 0.5 mg tablet, Rexulti 1 mg tablet, Rexulti 2 mg tablet, Rexulti 3 mg tablet, Rexulti 4 mg tablet	QL Addition	Non-Preferred Brand		12/01/21

Risperdal 3 mg tablet	QL Deletion	Non-Preferred Brand		12/01/21
Risperidone 3 mg tablet	QL Deletion	Generic		12/01/21
Sertraline 20 mg/mL concentrate	QL Addition	Generic		12/01/21
Thioridazine 50 mg tablet	QL Deletion	Generic		12/01/21
Venlafaxine 100 mg tablet, Venlafaxine 25 mg tablet, Venlafaxine 50 mg tablet, Venlafaxine 75 mg tablet	QL Addition	Generic		12/01/21
Venlafaxine 75 mg capsule, ER 24 hr, Venlafaxine ER 150 mg capsule, ER 24 hr	QL Update	Generic		12/01/21
Viibryd 10 mg (7)-20 mg (23) tablets in a dose pack	PA Deletion; QL Addition	Non-Preferred Brand		12/01/21
Viibryd 10 mg tablet, Viibryd 40 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Wellbutrin SR 100 mg tablet, Wellbutrin SR 150 mg tablet, Wellbutrin SR 200 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Zoloft 20 mg/mL concentrate	QL Addition	Non-Preferred Brand		12/01/21
Aubagio 14 mg tablet, Aubagio 7 mg tablet	Formulary Update	Non-Preferred Brand		12/01/21
Bafiertam 95 mg DR capsule	PA Addition	Preferred Brand		12/01/21
Briviact 10 mg tablet, Briviact 25 mg tablet, Briviact 50 mg tablet, Briviact 75 mg tablet, Briviact 10 mg/mL solution	QL Addition	Non-Preferred Brand		12/01/21
Carbamazepine 100 mg capsule, ER multiphase 12hr, Carbamazepine 200 mg capsule, ER multiphase 12hr, Carbamazepine 300 mg capsule, ER multiphase 12hr, Carbamazepine 100 mg tablet, ER 12 hr,	QL Addition	Generic		12/01/21

Carbamazepine 100 mg chewable tablet, Carbamazepine 200 mg tablet, Carbamazepine 100 mg/5 mL (5 mL) suspension, Carbamazepine 100 mg/5 mL suspension, Carbamazepine 200 mg/10 mL suspension				
Carbatrol 100 mg capsule, ER multiphase 12hr, Carbatrol 200 mg capsule, ER multiphase 12hr, Carbatrol 300 mg capsule, ER multiphase 12hr	QL Addition	Non-Preferred Brand		12/01/21
Clobazam 2.5 mg/mL suspension	QL Addition	Generic		12/01/21
Copaxone 20 mg/mL subcutaneous syringe, Copaxone 40 mg/mL subcutaneous syringe	Formulary Update	Non-Preferred Brand		12/01/21
Epidiolex 100 mg/mL solution	Formulary Update	Non-Preferred Brand		12/01/21
Epitol 200 mg tablet	QL Addition	Generic		12/01/21
Ingrezza 60 mg capsule	Specialty Addition	Preferred Brand		12/01/21
Keppra 100 mg/mL solution	QL Addition	Non-Preferred Brand		12/01/21
Lamotrigine 250 mg tablet, ER 24 hr	QL Addition	Generic		12/01/21
Levetiracetam 100 mg/mL solution, Levetiracetam 500 mg/5 mL (5 mL) solution	QL Addition	Generic		12/01/21
Mavenclad (10 tablet pack) 10 mg tablet, Mavenclad (4 tablet pack) 10 mg tablet, Mavenclad (5 tablet pack) 10 mg tablet, Mavenclad (6 tablet pack) 10 mg tablet, Mavenclad (7 tablet pack) 10 mg tablet,	QL Addition	Non-Preferred Brand		12/01/21

Mavenclad (8 tablet pack) 10 mg tablet, Mavenclad (9 tablet pack) 10 mg tablet				
Mayzent starter pack 0.25 mg (12 tabs) tablets, Mayzent 0.25 mg tablet, Mayzent 2 mg tablet	QL Addition	Non-Formulary	Gilenya 0.5 mg capsule, Zeposia starter pack 0.23 mg (4)-0.46 mg (3) capsules in a dose pack	12/01/21
Memantine 5-10 mg tablet, dose pack	QL Addition	Generic		12/01/21
Namenda titration pak 5-10 mg tablet, dose pack	QL Addition	Non-Preferred Brand		12/01/21
Ocrevus 30 mg/mL IV (ml)	Formulary Update	Non-Preferred Brand		12/01/21
Onfi 2.5 mg/mL suspension	QL Addition	Non-Preferred Brand		12/01/21
Oxtellar XR 150 mg tablet, ER 24 hr, Oxtellar XR 300 mg tablet, ER 24 hr	QL Addition	Non-Preferred Brand		12/01/21
Plegridy 125 mcg/0.5 mL IM syringe (ml), Plegridy 125 mcg/0.5 mL subcutaneous syringe (ml), Plegridy 63 mcg/0.5 mL- 94 mcg/0.5 mL subcutaneous syringe (ml) Plegridy 125 mcg/0.5 mL subcutaneous pen injector (ml), Plegridy 63 mcg/0.5 mL- 94 mcg/0.5 mL subcutaneous pen injector (ml)	Formulary Update	Non-Preferred Brand		12/01/21
Ponvory 14-day starter pack 2 mg (2) - 10 mg (3) tablet, dose pack	QL Addition	Non-Preferred Brand		12/01/21
Ponvory 20 mg tablet	QL Update	Non-Preferred Brand		12/01/21
Sabril 500 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Tegretol XR 100 mg ER tablet, Tegretol 200 mg tablet, Tegretol 100 mg/5 mL suspension	QL Addition	Non-Preferred Brand		12/01/21

Topamax 25 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Topiramate 25 mg tablet	QL Addition	Generic		12/01/21
Vigabatrin 500 mg tablet	QL Addition	Generic		12/01/21
Vimpat 100 mg tablet, Vimpat 150 mg tablet, Vimpat 200 mg tablet	QL Addition	Preferred Brand		12/01/21
Vumerity 231 mg DR capsule	Formulary Addition; QL Addition	Non-Preferred Brand		12/01/21
Zonegran 25 mg capsule	QL Addition	Non-Preferred Brand		12/01/21
Zonisamide 25 mg capsule, Zonisamide 50 mg capsule	QL Addition	Generic		12/01/21
Cabenuva 600 mg/3 mL-900 mg/3 mL ER suspension IM	Formulary Addition; PA Addition; QL Addition	Non-Preferred Brand		12/01/21
Epclusa 400-100 mg tablet	Formulary Update	Non-Preferred Brand		12/01/21
Epinephrine 0.15 mg/0.3 ml auto-injector (ea) injection	QL Addition	Generic		12/01/21
Epipen 2-pak 0.3 mg/0.3 ml auto-injector (ea) injection, Epipen jr 2-pak 0.15 mg/0.3 ml auto-injector (ea) injection	QL Addition	Non-Preferred Brand		12/01/21
Evkeeza 150 mg/mL (mL) IV	Specialty Addition	Preferred Brand		12/01/21
Harvoni 33.75-150 mg pellets in packet (ea), Harvoni 45-200 mg pellets in packet (ea), Harvoni 45-200 mg tablet, Harvoni 90-400 mg tablet	Formulary Update	Non-Preferred Brand		12/01/21
Intelence 100 mg tablet, Intelence 200 mg tablet, Intelence 25 mg tablet	Formulary Update	Non-Preferred Brand		12/01/21
Jynarque 15 mg (am)/ 15 mg (pm) tablet, sequential, Jynarque 30 mg (am)/ 15 mg (pm) tablet, sequential, Jynarque 45 mg (am)/ 15 mg (pm) tablet, sequential,	QL Update	Non-Preferred Brand		12/01/21

Jynarque 60 mg (am)/ 30 mg (pm) tablet, sequential, Jynarque 90 mg (am)/ 30 mg (pm) tablet, sequential, Jynarque 15 mg tablet				
Jynarque 30 mg tablet	QL Addition	Non-Preferred Brand		12/01/21
Omeprazole 20 mg - sodium bicarbonate 1680 mg packet, Omeprazole 40 mg - sodium bicarbonate 1680 mg packet	Formulary Addition, Age Edit Addition	Generic		12/01/21
Palforzia (level 1) 3 mg (1 mg x 3) sprinkle capsule, Palforzia (level 2) 6 mg (1 mg x 6) sprinkle capsule, Palforzia (level 3) 12 mg (1 mg x 2, 10 mg x 1) sprinkle capsule, Palforzia (level 4) 20 mg sprinkle capsule, Palforzia (level 5) 40 mg (20 mg x 2) sprinkle capsule, Palforzia (level 6) 80 mg (20 mg x 4) sprinkle capsule, Palforzia (level 7) 120 mg (20 mg x 1, 100 mg x 1) sprinkle capsule, Palforzia (level 8) 160 mg (20 mg x 3, 100 mg x1) sprinkle capsule, Palforzia (level 9) 200 mg (100 mg x 2) sprinkle capsule, Palforzia (level 10)240 mg (20 mg x 2, 100 mg x 2) sprinkle capsule, Palforzia (level 11 up-dose) 300 mg powder in packet (ea), Palforzia level 11 maintenance 300 mg powder in packet (ea), Palforzia initial dose 0.5/1/1.5/3/6 mg sprinkle capsule	Specialty Addition	Preferred Brand		12/01/21
Ridaura 3 mg capsule	Specialty Addition	Preferred Brand		12/01/21
Sunosi 150 mg tablet, Sunosi 75 mg tablet	Specialty Addition	Non-Formulary	Nuvigil 50 mg tablet, Nuvigil 150 mg tablet, Nuvigil 200 mg tablet, Nuvigil 250 mg tablet; Provigil 100 mg tablet, Provigil 200 mg tablet	12/01/21

Legend: AL=Age Limit; OTC=Over-The-Counter; PA=Prior Authorization; SP=Specialty; ST=Step Therapy; QL=Quantity Limit; NF=Non-Formulary; SPS=Smallest Package Size;

New Prior Authorization Policies

- RxA.688.Tazorac
- RxA.689.Vocabria_Cabenuva
- RxA.690.Rybrevant
- RxA.691.Truseltiq
- RxA.692.Empaveli
- RxA.693.Camcevi
- RxA.694.Zynrelef
- RxA.695.Lumakras
- RxA.696.Myfembree
- RxA.697.Lybalvi
- RxA.698.Bylvay
- RxA.699.Kerendia
- RxA.700.Rezurock
- RxA.701.Saphnelo
- RxA.702.Twyneo
- RxA.703.Rylaze

Updated Prior Authorization Policies

Policy Name	Policy Changes	Effective Date
RxA.127.Farydak	Initial Approval Criteria, I.A.5.b and I.A.5.c: Updated to indicate that combination therapies listed are considered to be off-label. Initial Approval Criteria, I.A.7: Updated to include NCCN disclaimer regarding relevant off-label use.	12/01/21
RxA.161.Harvoni	Dosing Information, Dosing Regimen, HCV Genotype 1: Updated to include “ledipasvir 90mg/sofosbuvir 400mg orally once daily” under Adult (age 18+). Dosing Information, Dosing Regimen, HCV Genotype 1: Treatment duration was updated from “Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) whose HCV viral load is less than 6 million IU/mL: For 8 weeks (12 weeks for black and/or HIV-coinfected patients)” to “Treatment-naïve without cirrhosis, HIV uninfected or whose HCV viral load is less than 6 million IU/mL: for 8 weeks.”. Dosing Information, Dosing Regimen, HCV Genotype 1 or 4: Updated to include “ledipasvir 90mg/sofosbuvir 400 mg orally once daily” under Adult (age 18+). Dosing Information, Dosing Regimen, HCV Genotype 4, 5, or 6: Updated to include “ledipasvir 90mg/sofosbuvir 400 mg orally once daily” under Adult (age 18+).	12/01/21

	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Units were updated from days/weeks to “6 months”. Appendix B, Dosing Regimen, Epclusa and Mavyret: Primary indication was updated from “HCV Genotype 1, 4, 5, or 6” to “HCV Genotype 1,2, 3, 4, 5, or 6”. Appendix B, Dosing Regimen, Mavyret: Updated from “Treatment-naïve: [Without cirrhosis: 3 tablets PO once daily for 8 weeks] / [With compensated cirrhosis: 3 tablets PO once daily for 12 week]” to “Treatment-naïve: [Without cirrhosis or with compensated cirrhosis: 3 tablets orally once daily for 8 weeks] / [With compensated cirrhosis and HIV coinfection: 3 tablets orally once daily for 12 weeks]”. Appendix B, Dosing Regimen, Zepatier: Updated to include “…and HIV coinfection” pertaining to indications Genotype 1a, Genotype 1b, and Genotype 4. Appendix B, Dosing Regimen, Zepatier: Updated from “Virologic failure while on pegIFN/RBV therapy” to “Virologic failure after receiving pegIFN/RBV therapy”. Appendix D: Updated to remove inactive/unavailable drug names Daklinza, daclatasvir, Olysio, and simeprevir. Appendix D: Updated to include footnote “*Combination drug”.	
RxA. 172.Ingrezza	Background: Updated indication to state that Ingrezza is a “reversible inhibitor” and to define vesicular monoamine transporter 2 as “a transporter that regulates monoamine uptake from the cytoplasm to a synaptic vesicle for storage and release”. Dosing Information, Doing Regimen: Updated to change primary dosing information from as needed dosing to initial dosing. Dosage Forms: Updated to include 60mg dose. Initial Approval Criteria, I.A.6: Updated to include “At the time of request, no documented congenital long QT syndrome…”. Continued Therapy Approval Criteria, II.A.5: Updated to include “No documentted congenital QT long syndrome or arrythmias associated…”. Appendix D: Updated to include “Valbenazine may cause parkinsonism in patients with tardive dyskinesia…”. Appendix F, Antiemetic Agents Column: Updated to remove	12/01/21

	"thiethylperazine."	
RxA. 182.Krystexxa	Appendix A: Updated to include abbreviation "PEGylated". Appendix B, Maximum Dose, allopurinol (Zyloprim®): Updated from "600 mg/day" to "800 mg/day". Appendix B, Maximum Dose, febuxostat (Uloric®*): Updated from "80 mg/day" to "120 mg/day". Appendix B, Drug Name: Updated to remove currently unavailable generic drug name "lesinurad". Appendix B, Drug Name: Updated to remove discontinued brand-name drug Zurampic. Appendix D, Warnings and Precautions: Updated to include warnings and precautions regarding a. Anaphylaxis b. Infusion Reactions c. G6PD Deficiency Associated Hemolysis and Methemoglobinemia d. Gout Flares e. Congestive Heart Failure f. Discontinue oral urate-lowering agents.	12/01/21
RxA. 208.Mircera	Appendix A: Updated to include abbreviation PRCA. Appendix B, Dosing Regimen and Maximum Dose: Updated to include alternative brand-name drug Epogen®. Appendix C, Contraindications: Updated to include "History of serious or severe allergy reactions to Micerna…". Appendix D, Warnings and Precautions: Updated to include "Epogen increases the risk for seizures in patients with CKD…".	12/01/21
RxA.219. Mirvaso	Initial Approval Criteria, I.A.2: Updated to include prescriber criteria, "Prescribed by or in consultation with a dermatologist…". Appendix B, Maximum Dose, doxycycline (Oracea®): Updated to remove "300 mg/day for Oracea.".	12/01/21

RxA. 227.Mestinon	Clinical Policy Title: Updated to include “oral solution”. Background: Updated to remove “Prior authorization is required for the oral syrup”. Dosing Information, Drug Name: Updated from “syrup” to “solution”. Dosage Forms: Updated from “syrup” to “solution”. Appendix C, Contraindications: Updated to include “Care should be observed in the use of atropine for counteracting side effects.”. Appendix D: Updated to include “The safety of Mestinon® during pregnancy or lactation in humans has not been established. Therefore, use of Mestinon® in women…”.	12/01/21
RxA.236. Neo-Synalar	Appendix D: Updated to include “If local infection should continue or become severe….”.	12/01/21
RxA.237.Nexavar	Initial Approval Criteria, I.A.5: Updated to include “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…”. Initial Approval Criteria, I.I.1.b: Updated to include “…therapy for 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)”. Initial Approval Criteria, I.I.1.b.i: Updated to include “Ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid;”. Initial Approval Criteria, I.I.1.b.ii: Updated to include “Documented progression in anatomic location where progression would be morbid;”. Initial Approval Criteria, I.I.1.b.iii: Updated to include “No documented progression in anatomic location where progression would be morbid if concerns for morbidity or significant symptoms;”. Appendix A: Updated to include abbreviation FLT3-ITD. Appendix B, Drug Name: Updated to remove inactive/unavailable drugs cabozantinib, sunitinib, and regorafenib.	12/01/21
RxA.247. Palynziq	Dosing Information, Dosing Regimen: Updated from “Initiate dosing with 2.5 mg SC once weekly for 4 weeks. Administer …”	12/01/21

	to "Consider increasing the dosage to a maximum of 60 mg once daily in patients who have been on 40 mg once daily continuously for at least 16 weeks and who have not achieved blood Phe control…". Dosing Information, Maximum Dose: Updated from "40 mg/day" to "60 mg/day". Initial Approval Criteria, I.A.6: Updated from "20 mg per day" to "40 mg per day". Continued Therapy Approval Criteria, II.A.2.c: Updated from "Member has been using 20 mg per day for at least 6 months, but a dose titration to 40 mg per day is being…" to "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.". Appendix B, Drug Name and Dosing Regimen and Maximum Dose: Updated to include alternative drug "sapropterin (Kuvan®)". Appendix C, Boxed Warnings: Updated to include "Anaphylaxis.".	
RxA.252. Poteligeo	Initial Approval Criteria, I.B.1: Updated indication from "adult T-cell leukemia/lymphoma" to "relapsed or refractory adult T-cell leukemia/lymphoma". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviations HDT, ASCR, mAb, and ADCC. Appendix B, Drug Name: Updated to remove inactive generic drug name "brentuximab vedotin" and to instead include its comparable Brand name drug "Adectris".	12/01/21
RxA.265.Epogen_Procrit_ Retacrit	Dosing Information, Dosing Regimen and Maximum Dose: Updated to remove off-label indications "anemia associated with MDS" and "anemia associated with myelofibrosis". Dosage Forms: Updated from table format to bullet-list format. Initial Approval Criteria, I.C.2: Updated to include "Diagnosis of moderate to severe chronic kidney disease". Initial Approval Criteria, I.C.3: Updated to include "Member is undergoing palliative treatment and refused blood transfusions".	12/01/21

	Initial Approval Criteria, I.C.4: Updated to include "Member has a minimum of two additional months of planned chemotherapy". Initial Approval Criteria, I.C , Approval Duration: Updated from "until the completion of chemotherapy course or 6 months, whichever is long" to "6 months". Appendix A: Updated to remove abbreviation SC. Appendix D, General Information: Updated to include warnings and precautions regarding a. Using ESAs to target a hemoglobin level of greater than 11 g/dL increase the risk of serious adverse b. Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence in Patients with Cancer c. Control hypertension prior to initiating and during treatment with ESAs d. Epoetin alfa products increase the risk for seizures in patients with CKD e. If severe anemia and low reticulocyte count develop during ESAs treatment f. Serious Allergic Reactions: Discontinue ESAs and manage reactions g. Severe Cutaneous Reactions: Discontinue ESAs.	
RxA.279.Seroquel_XR	Dosing Information, Footnote: Updated to include "*Hepatic Impairment: Lower starting dose (50 mg/day) and slowly increase dose by 50 mg once daily to effective dose.". Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B, Maximum Dose, fluvoxamine: Updated from "150mg/day" to "300mg/day". Appendix B, Drug Name: Updated to remove inactive/unavailable drugs Luvox, Elavil, Sinequan, Tofranil, Tofranil PM, Vivactil, Surmontil, Budeprion SR, Budeprion XL, Wellbutrin, Triavil, Ludiomil, Serzone, Desyrel, Oleptro, vortioxetine, and vilazodone. Appendix B, Maximum Dose, paroxetine: Updated from "50mg/day" to "60mg/day" for immediate-release formulation and updated from "62.5mg/day" to "75mg/day" for extended-release formulation.	12/01/21

	Appendix B, Maximum Dose, sertraline: Updated to remove age criteria, “if age 6-12 years”. Appendix B, Maximum Dose, maprotiline: Updated from “150mg/day” to “225mg/day”. Appendix D, Warnings and Precautions: Updated to include “Concomitant use of strong CYP3A4 inhibitors: Reduce quetiapine…”, “Concomitant use of strong CYP3A4 inducers: Increase quetiapine dose…”, and “Discontinuation of strong CYP3A4 inducers: Reduce quetiapine…”.	
RxA.282.Sitavig_Avaclyr	Initial Approval Criteria, I.A.4.a.1 through I.A.4.a.3: Consolidated into I.A.4.a. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only".	12/01/21
RxA.289.Ultomiris	Background: Updated from “treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)” to “treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)”. Dosing Information, Dosing Regimen: Updated from table format to bullet-list format. Dosing Information, Dosing Regimen, PNH: Updated to include dosing for lower body weights a. Body weight 5 to < 10 kg b. Body weight 10 to < 20 kg c. Body weight 20 to < 30 kg d. Body weight 30 to < 40 kg. Dosing Information, Dosing Regimen, aHUS: Updated from “…administer maintenance doses intravenous once every 8 weeks, starting 2 weeks after loading dose administration” to “…administer maintenance doses intravenous once every 4 weeks or 8 weeks (depending on body weight), starting 2 weeks after loading dose administration.”. Dosage Forms: Updated from “single-dose vial: 300mg/30mL” to “300 mg/30 mL (10 mg/mL) in a single-dose vial; 300 mg/3 mL (100 mg/mL) in a single-dose vial; 1,100 mg/11 mL (100 mg/mL) in a single-dose vial.”. Initial Approval Criteria, I.A.3: Updated from “Age ≥ 18 years” to “Age ≥ 1 month”.	12/01/21

	Initial Approval Criteria, I.A.6.b: Updated from listing specific weight-based loading doses (in mg) to "Loading dose (Day 1) does not exceed the weight based loading dose in the Dosing Information;". Initial Approval Criteria, I.A.6.c: Updated from listing specific weight-based maintenance doses (in mg) to "Maintenance dose (Day 15 and every 4 or 8 weeks thereafter) does not exceed the weight based maintenance dose in the Dosing Information;". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria, II.A.3: Updated from listing specific weight-based maintenance doses (in mg) to "If request is for a dose increase, new dose does not exceed the weight-based maintenance dose in the Dosing Information". Appendix A: Updated to include abbreviation LDH. Appendix C, Contraindications: Updated to include "Patients who are not currently vaccinated against *Neisseria meningitidis*....".	
RxA.303.Xadago	Appendix B, Maximum Dose, Stalevo: Updated from "1200mg daily (divided doses)" to "300 mg/day orally carbidopa; 1,200 mg/day orally levodopa; 1,600 mg/day orally of entacapone". Appendix B, Drug Name: Updated to remove discontinued drugs Requip and Requip XR and to remove inactive/unavailable drug rotigotine.	12/01/21
RxA.305.Xermelo	Appendix D: Updated to include "Constipation: Xermelo® reduces bowel movement frequency; monitor patients…".	12/01/21
RxA.312.Xeomin	Background: Updated to remove "…adult patients with…". Background: Updated to include "…in patients 2 years of age and older;" and "Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy;". Background: Updated to include "…in adults" after points "upper limb spasticity", "cervical dystonia", and "blepharospasm". Dosing Information, Dosing Regimen, Chronic Sialorrhea: Updated to remove "The recommended total dose per treatment session is 100 Units". Dosing Information, Dosing Regimen, Chronic Sialorrhea: Updated to include specific adult and pediatric dosing tables.	12/01/21

	Dosing Information, Maximum Dose ,Chronic Sialorrhea: Updated from “One treatment period per 16 weeks; 100 units per treatment session consisting: Parotid gland(s): 60 units (30 units per side); Submandibular gland(s): 40 units (20 units per side)” to “Adults: Max 100 units per treatment session; Pediatric: 75 units”. Dosing Information, Dosing Regimen, Cervical Dystonia: Updated to include “…Administer no more frequently than every 3 months”. Dosing Information, Dosing Regimen, Blepharospasm: Updated to include “…no more frequently than every 3 months”. Dosing Information, Dosing Regimen, Upper limb Spasticity: Updated to include “Adults: the recommended total dose is up to 400 Units, divided among affected muscles / Pediatric Patients, excluding spasticity caused by cerebral palsy: the recommended total dose is 8 Units/kg (maximum 200 Units) per single upper limb or 16 Units/kg (maximum 400 U) in both upper limbs, divided among affected muscles. Administer no more frequently than every 3 months”. Dosing Information, Dosing Regimen and Maximum Dose: Updated to include indication “Glabellar Lines”. Dosage Forms: Updated from “Vials: 50 units, 100 units, 200 units” to “Injection: 50 Units, 100 Units, or 200 Units lyophilized powder in a single-dose vial”. Initial Approval Criteria, I.A.5: Updated from “Dose does not exceed 100 unites per treatment session” to “Dose does not exceed one of the following (a or b)…”. Initial Approval Criteria, I.A.5.a and I.A.5.b: Updated to include “For Adults: 100 units per treatment session” and “For Pediatric: 75 units per treatment session” respectively. Initial Approval Criteria, I.D.3: Updated from “Age 18 years of age or older” to “Member meets one of the following (a or b)…” Initial Approval Criteria, I.D.3.a and I.D.3.b: Updated to include “Age 2 to 17 years of age excluding spasticity caused by cerebral palsy” and “Age ≥ 18 years” respectively. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Units were updated from weeks to days.	

	Continued Therapy Approval Criteria, II.A.5.a: Updated from "Chronic sialorrhea: 100 units per treatment session" to "Chronic sialorrhea (i or ii)". Continued Therapy Approval Criteria, II.A.5.a.i and II.A.5.a.ii were updated to include "Adult: 100 units per treatment session" and "Pediatric: 75 units per treatment session" respectively. Appendix B: Updated to include Therapeutic Alternatives table. Appendix B, Dosing Regimen and Maximum Dose: Updated to include alternative drugs Botox® (onabotulinumtoxinA) and Botox cosmetic.	
RxA.320.Xeloda	Initial Approval Criteria, I.D: Updated to remove off-label NCCN category-3 indication, "Bladder Cancer (off-label)". Initial Approval Criteria, I.D.4: Updated from "Prescribed in one of the following ways: a. As monotherapy with or without radiation or b. In combination with oxaliplatin;" to "Prescribed as monotherapy with or without radiation or as a component of CAPEOX regimen;". Initial Approval Criteria, I.D.5: Updated to include "Prescribed for symptomatic patients with performance status (PS) 1-2 or asymptomatic patients with PS 0 and aggressive disease;". Initial Approval Criteria, I.E.4.b: Updated from "In combination with cisplatin, oxaliplatin, or paclitaxel or" to "In combination with cisplatin or oxaliplatin". Initial Approval Criteria, I.E.4.c: Updated from "In combination with epirubicin and either cisplatin or oxaliplatin" to "In combination with cisplatin and trastuzumab". Initial Approval Criteria, I.E.4.d: Updated to include "In combination with cisplatin and pembrolizumab (PD-L1 CPS ≥ 10) for adenocarcinoma…". Initial Approval Criteria, I.E.4.e: Updated to include "In combination with oxaliplatin and nivolumab (PD-L1 CPS ≥ 5) for adenocarcinoma…". Initial Approval Criteria, I.E.4.f: Updated to include "In combination with oxaliplatin and pembrolizumab (PD-L1 CPS ≥ 10) for adenocarcinoma…". Initial Approval Criteria, I.E.5: Updated to include "Prescribed for patients with Karnofsky performance score ≥ 60% or ECOG performance score ≤ 2;".	12/01/21

	Initial Approval Criteria, I.F.4.b: Updated from “In combination with cisplatin, oxaliplatin, or paclitaxel or” to “In combination with cisplatin, trastuzumab, pembrolizumab, or oxaliplatin”. Initial Approval Criteria, I.F.4.c: Updated from “In combination with epirubicin and either cisplatin or oxaliplatin” to “In combination with oxaliplatin and nivolumab (PD-L1 CPS ⩾ 5) (if no prior tumor progression while on therapy with a checkpoint inhibitor)”. Initial Approval Criteria, I.F.6: Updated to include “Prescribed for patients with Karnofsky performance score ≥ 60% or ECOG performance score ≤ 2;”. Initial Approval Criteria, I.G.3: Updated to include age criteria, “Age ≥ 18 years;”. Initial Approval Criteria, I.I.4.a: Updated from “As monotherapy” to “As monotherapy with or without concurrent chemoradiation”. Initial Approval Criteria, I.I.4.c: Updated to include “Treatment for resected disease”. Initial Approval Criteria, I.J: Indication was updated from “Neuroendocrine Tumors (off-label)” to “Neuroendocrine and Adrenal Tumors (off-label)”. Initial Approval Criteria, I.J.4: Updated to include “…or as a component of CAPEOX regimen”. Initial Approval Criteria, I.L.4.a: Updated from “As monotherapy with or without radiation therapy” to “As monotherapy for patients with locally advanced disease and good performance status (ECOG PS 0-1) or following neoadjuvant therapy”. Initial Approval Criteria, I.L.4.b: Updated to include “With radiation therapy”. Initial Approval Criteria, I.L.4.c: Updated from “In combination with gemcitabine with or without docetaxel” to “In combination with gemcitabine”. Initial Approval Criteria, I.L.4.d: Updated to include “…with good performance status (ECOG PS 0-1) and disease progression who were previously treated with gemcitabine-based therapy”. Initial Approval Criteria, I.M.4: Updated to include “…for non-metastatic disease”. Initial Approval Criteria, I.P: Updated to include off-label NCCN category-2A indication, “Squamous Cell Skin Cancer (off-label)”.	

	Appendix A: Updated to include abbreviations PS, ECOG, HER2, INR, and PD-L1 CPS. Appendix D, General Information: Updated to include information regarding a. Patients receiving concomitant Xeloda® and oral coumarin-derivative b. Occurrence: Within several days and up to several months c. Predisposing factors: age > 60 years and diagnosis of cancer. Appendix D: Updated to include Reference for CPS and subsequent data table. Appendix D: Updated to include Reference Index for Performance Score" and subsequent data table.	
RxA.324.Yondelis	Dosing Information, Dosing Regimen: Updated to include hepatic dosing, "Hepatic impairment: Administer at 0.9 mg/m2 body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line in patients with moderate hepatic impairment". Initial Approval Criteria, I.A.1: Updated to include "…(see Appendix D for examples)". Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix D: Updated to include "Indication covered under initial approval criteria: Soft tissue sarcoma: Extremity/Body Wall, Head/Neck; Retroperitoneal/Intra-Abdominal; Rhabdomyosarcoma; Angiosarcoma; Solitary Fibrous Tumor / Uterine Neoplasms - Uterine Sarcoma".	12/01/21
RxA.325.Zytiga_Yonsa	Dosing Information, Indication: Updated to include "Prostate cancer". Dosing Information, Dosing Regimen: Updated to include indications CRPC and CSPC. Dosing Information, Dosing Regimen: Updated to include hepatic impairment dosing, "Hepatic impairment: (Child-Pugh Class B), reduce the YONSA starting dose to 125 mg once daily". Dosage Forms: Updated from table format to bullet-list format. Initial Approval Criteria, I.A.5.a: Updated to include "Can use dexamethasone 1 mg/day in place of prednisone".	12/01/21

	Initial Approval Criteria, I.A.6.a.i: Updated to include "Can use dexamethasone 1 mg/day in place of methylprednisolone". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix C, Contraindications: Updated to remove "Pregnancy (Yonsa® only)".	
RxA.326.Yupelri	Initial Approval Criteria, I.A.1.a: Updated to include "At least GOLD group B". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21
RxA.327.Zaltrap	Initial Approval Criteria, I.A.4: Updated from "Previous treatment with one of the following (a, b, or c)…" to "Previous treatment with an oxaliplatin-containing regimen (e.g., FOLFOX, CapeOX)". Initial Approval Criteria, I.A.4.a-c: Updated to remove "An oxaliplatin-containing regimen (e.g., FOLFOX, CapeOX)", "A 5-fluorouracil and leucovorin-containing regimen (off-label)", and "A capecitabine-containing regimen (off-label)" respectively. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria, Approval Duration: Updated from "12 months" to "6 months" for Medicaid. Appendix B, Dosing Regimen, Modified FOLFOX6: Updated from "Day 1: oxaliplatin 100 mg/m2 IV" to "Day 1: oxaliplatin 85 mg/m2 intravenously". Appendix B, Dosing Regimen, Modified FOLFOX6: Updated to include "…Give before 5-FU" and "…over 2 hours with oxiplatin. Give before 5-FU…". Appendix B, Dosing Regimen, CapeOX: Updated from "Days 1–14: Capecitabine 1,000 mg/m^2 PO BID" to "Days 1–14: Capecitabine 850 mg/m^2 orally twice daily". Appendix B, Dosing Regimen, FOLFIRI: Updated from "Day 1: Flurouracil 400 mg/m^2 IV followed by 2400 mg/m^2 continuous IV over 46 hours" To "Day 1: Flurouracil 400 mg/m^2 IV followed by 2400 mg/m^2 continuous IV over 46-48 hours". Appendix B, Dosing Regimen, 5-fluorouracil and leucovorin: Updated from "Biweekly regimen: Leucovorin 400 mg/m2 IV on day one followed by 5-FU 400 mg/m2 IV bolus then 1,200 mg/m2 continuous IV. Repeat every 2 weeks" to "Biweekly	12/01/21

	regimen: Leucovorin 400 mg/m^2 intravenously on day one followed by Flurouracil 400 mg/m^2 intravenously on day 1, followed by 2400 mg/m^2 continuous intravenously over 46-48 hours. Repeat cycle every 14 days". Appendix B, Dosing Regimen, 5-fluorouracil and leucovorin: Weekly regimen was updated to include "…over 24 hours…". Appendix C, Boxed Warning: Updated to remove "Hemorrhage, gastrointestinal perforation, compromised wound healing". Appendix D, Warnings and Precautions: Updated to include "Hemorrhage: Severe and sometimes fatal hemorrhage…", "Gastrointestinal Perforation: Discontinue Zaltrap® therapy…", "Impaired Wound Healing: Withhold Zaltrap® for at least 4 weeks prior…", "Fistula Formation: Discontinue Zaltrap® if fistula occurs", "Hypertension: Monitor blood pressure and treat hypertension…", "Arterial Thromboembolic Events (ATE): Discontinue Zaltrap® if ATE develops", "Proteinuria: Monitor urine protein. Suspend ZALTRAP for proteinuria…", "Neutropenia and Neutropenic Complications: Delay administration of Zaltrap®/Folfiri…", "Diarrhea and Dehydration: Incidence of severe diarrhea and dehydration…", "Reversible Posterior Leukoencephalopathy Syndrome: Discontinue Zaltrap®", and "Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of potential risk…".	
RxA.328.Zilretta	Clinical Policy Title, Drugs Applied: Updated to remove inactive/unavailable drug "Triamcinolone ER Injection". Clinical Policy Title, Line of Business Policy Applies to: Updated from "Commercial, Medicaid, HIM-Medical Benefit" to "All lines of business". Background: Updated to include Limitations of Use, "Limitation of use: The efficacy and safety of repeat administration of Zilretta® have not been demonstrated". Initial Approval Criteria, I.A.4: Updated from "Failure of ≥ 2 week trial of one of the following…" to "Failure of ≥ 4 week trial of one of the following…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B, Drug Name: Updated to remove inactive/unavailable drugs Anaprox and Anaprox DS.	12/01/21
RxA.329.Totect	Clinical Policy Title, Drugs Applied: Updated to remove inactive/unavailable drug Zinecard.	12/01/21

	Background: Updated to include "Do not use Totect® with doxorubicin initiation". Dosing Information: Updated to remove inactive/unavailable drug Zinecard. Dosing Information, Dosing Regimen, Doxorubicin Induced Cardiomyopathy: Updated from "Give Zinecard at a ratio of 10:1 with the doxorubicin dose as an IV infusion over 15 minutes and within 30 minutes before doxorubicin is given" to "Give dexrazoxane at a ratio of 10:1 with the doxorubicin dose as an intravenous infusion over 15 minutes. Give doxorubicin within 30 minutes after completion of dexrazoxane dose". Dosage Forms: Updated to remove inactive/unavailable drug name Zinecard. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	
RxA.330.Zinplava	No Update.	12/01/21
RxA.331.Aczone	Dosage Forms: Updated to remove 30g tube and pump. Appendix B, Dosing Regimen, Adapalene: Updated to include dosage forms solution, swab, and jelly. Appendix B, Dosing Regimen, Tretinoin: Updated to include dosage forms 0.06% and 0.08%. Appendix B: Updated to remove "Foam 1%: apply topically once daily…". Appendix B, Footnote: Updated to include "*The American Academy of Dermatology acne guidelines recommend…".	12/01/21
RxA.332.Adcirca_Alyq	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B: Updated to remove inactive/unavailable drugs Afeditab® CR and Dilacor XR®. Appendix D: Updated to include "Dividing the 40mg dose over the course of the day is not recommended".	12/01/21
RXA.335.Alecensa	Background: Rephrased to "Alectinib (Alecensa®)is a kinase inhibitor indicated for the treatment…". Initial Approval Criteria, I.B: Updated to include off-label indication, "CNS Cancer (Limited & Extensive Brain Metastases) (Off -Label) …". Continued Therapy Approval Criteria, II.A: Updated from "Non	12/01/21

	Small Cell Lung Cancer" to "All indications in Section I…" Appendix A was updated to include abbreviations ILD, CNS, ALT, and AST. Appendix D, Warnings and Precautions: Updated to include "Hepatotoxicity…", "Interstitial Lung Disease…", "Renal impairment…", "and "Bradycardia…".	
RxA.336.Ampyra	Initial Approval Criteria and Continued Therapy Approval Criteria , Approval Duration: Updated to remove HIM. Initial Approval Criteria, I.A.5: Updated to include trial and failure criteria, " Trial and failure of at least two (2) preferred agents …" Appendix A was updated to include abbreviation OCT2. Appendix D was updated to include " Concurrent use with OCT2 inhibitors, such as cimetidine …"	12/01/21
RxA.338.Aripiprazole_orally_disintegrating_tablet	Clinical Policy Title, Drugs Applied: Updated to remove unavailable brand name drug Abilify Discmelt. Dosing Information, Dosing Regimen, Major Depressive Disorder: Updated from "Target: 5 to 10mg once daily" to "Target: 2 to 15 mg once daily". Initial Approval Criteria, I.A.1.b-e: Updated to remove indications a. Bipolar disorder b. Major depressive disorder c. Autistic disorder d. Tourette's disorder. Initial Approval Criteria, I.A.2: Updated from "Member meets one of the following (a, b, c, d, or e)" to "Member meets DSM-III/IV criteria". Initial Approval Criteria, I.A.2.b-e: Updated to remove "schizophrenia…", "bipolar disorder…", "major depressive disorder…", "autistic disorder…", and "Tourette's disorder…" respectively. Initial Approval Criteria, I.A.3: Updated to remove "Medical justification supports inability to use generic aripiprazole tablet and/or oral solution" due to brand-name drug inactivity (generic available only). Initial Approval Criteria, I.A.3: Updated to include "Documentation supports that member is unable to swallow, unable to absorb medications through the GI tract". Initial Approval Criteria, I.A.4: Updated to remove "For major depressive disorder, aripiprazole ODT will be used concurrently with an antidepressant".	12/01/21

	Initial Approval Criteria, I.A.4: Updated to include "Dose does not exceed 30mg per day". Initial Approval Criteria, I.A.5: Updated to remove indication-based and weight-based dosing requirements. Initial Approval Criteria, I.B: Updated to include indication "Bipolar Disorder". Initial Approval Criteria, I.C: Updated to include indication "Major Depressive Disorder". Initial Approval Criteria, I.D: Updated to include indication "Autistic Disorder". Initial Approval Criteria, I.E: Updated to include indication "Tourette's Syndrome". Appendix A: Updated to include abbreviation DSM. Appendix C, Boxed Warnings: Updated to include "Increased risk of suicidal thinking and behavior in children, adolescents, and young adults…". Appendix D: Updated to include "Aripiprazole ODT may cause extrapyramidal and/or withdrawal…" and "The Diagnostic and Statistical Manual of Mental Disorders (DSM) is the handbook…".	
RxA. 340.Addyi	Background: Updated to remove "is a serotonin 5 HT1A receptor agonist and a 5 HT2A receptor antagonist…". Appendix B: Updated to include drug "Vyleesi" and its dosing regimen, "1.75 mg SC in abdomen or thigh, as needed…". Appendix C, Boxed Warning: Updated to include "due to interaction with alcohol. Taking flibanserin within two hours after…".	12/01/21
RxA. 341.Aemcolo	Doing Information, Dosing Regimen: Updated to include "for three days.". Initial Approval Criteria, I.A.3.b: Updated to include "Fluoroquinone regimens, unless contraindicated or clinically significant…". Initial Approval Criteria, I.A.3.b.i: Updated to include "Ciprofloxacin 750 mg daily or 500 mg twice daily for 1-3 days.". Initial Approval Criteria, I.A.3.b.ii: Updated to include "Levofloxacin 500 mg once daily for 1-3 days.". Initial Approval Criteria, I.A.3.b.iii: Updated to include "Ofloxacin 400 mg once daily for 1-3 days.".	12/01/21

	Appendix B, Drug Name: Updated to include therapeutic alternatives ciprofloxacin, levofloxacin, and ofloxacin, in addition to their respective dosing information.	
RxA.345.Arakoda	Initial Approval Criteria, I.A.5: Updated to include "Patient must test negative for G6PD deficiency".	12/01/21
RXA.346.Aranesp	No Update.	12/01/21
RxA.347.Oncaspar_Asparlas	Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Initial Approval Criteria, I.B.1: Updated from "Diagnosis of NK/T-cell lymphoma, nasal type" to "Diagnosis of one of the following NK/T-cell lymphoma subtypes (a, b, or c)…". Initial Approval Criteria, I.B.1.a: Updated to include diagnosis Nasal Type NK/T-Cell Lymphoma. Initial Approval Criteria, I.B.1.b: Updated to include diagnosis Extranasal Type NK/T-Cell Lymphoma. Initial Approval Criteria, I.B.1.c: Updated to include diagnosis Aggressive NK-Cell Leukemia. Initial Approval Criteria, I.B.2: Updated to include criteria requiring request to be for Oncaspar. Initial Approval Criteria, I.B.5.c: Updated to include "DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase);". Initial Approval Criteria, I.C: Updated to include off-label indication Hepatosplenic T-Cell Lymphoma. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria, II.A.1: Rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Appendix D, Warnings and Precautions: Updated to include information regarding a. Hypersensitivity: Observe patients for one hour after administration b. Pancreatitis: Discontinue Asparlas™ in patients with pancreatitis c. Thrombosis: Discontinue Asparlas™ for severe or life-threatening thrombosis d. Hemorrhage: Discontinue Asparlas™ for severe or life-threatening hemorrhage	12/01/21

	e. Hepatotoxicity: Monitor for toxicity through recovery from cycle.	
RxA. 349.Austedo	Dosing Information, Maximum Dose: Updated to include ”strong CYP2D6 inhibitors”. Initial Therapy Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix C, Contraindications: Verbiage was rephrased as per PI.	12/01/21
RxA. 350.Alimta	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include NCCN. Appendix D, Warnings and Precautions: Updated to include “Myelosuppression: Can cause severe bone marrow suppression resulting in cytopenia…”.	12/01/21
RxA.352.Bendeka_Treanda_ Belrapzo	Clinical Policy Title, Drugs Applied: updated to include “Belrapzo®”. Dosing Information, Dosing Regimen: Updated to include “Belrapzo®: 100 mg/m2 intravenously over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles…”. Dosage Forms: Updated to include “bendamustine (Belrapzo®): Solution (multiple-dose vial): 100 mg/4 mL…”. Initial Approval Criteria, I.A.4.a.iii: Updated to include “Belrapzo®: 100 mg/m^2 intravenously over 30 minutes…”. Initial Approval Criteria, I.B.5.a.iii: Updated to include “Belrapzo®: 120 mg/m^2 intravenously on days…”. Initial Approval Criteria, I.C.1.f: Updated to include “Breast implant -associated anaplastic large cell lymphoma…”. Initial Approval Criteria, I.C.6: Updated to include “If the member has the diagnosis of Breast implant…”. Initial Approval Criteria, I.G: Updated to include prescribing criteria for new indication “Pediatric Hodgkin Lymphoma (off-label)…”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria, II.A.3.a.i.c: Updated to include “Belrapzo®: 100 mg/m^2 intravenously over 30 minutes…”	12/01/21

	Continued Therapy Approval Criteria, II.A.3.a.ii.c: Updated to include "Belrapzo®: 120 mg/m^2 intravenously on days 1…" Appendix A: Updated to include abbreviations ISRT, RT, CR1, and BIA-ALCL. Appendix D, Warnings and Precautions: Updated to include "Myelosuppression: Delay or reduce dose and restart treatment based on ANC and platelet count recovery…"	
RxA.354.Buphenyl	No Update	12/01/21
RxA.355.Basaglar	No Update	12/01/21
RxA.356.Baxdela	Dosing Information, Dosing Regimen: Updated to include renal dosing, "Renal dose adjustment (eGFR 15-20 mL/min/1.73 m^2): 200 mg every 12 hours Or 200 mg every 12 hours…". Dosing Information, Maximum Dose: Updated to include "5 – 14 days for ABSSSI" and "5 – 10 days for CABP". Initial Approval Criteria, I.A.1: Updated from "Diagnosis of ABSSSI & CABP" to "Diagnosis of ABSSSI or CABP". Appendix B, Drug Name: Updated to include "fluoroquinolone antibiotics"; its dosing regimen and maximum dose was updated to include "varies". Appendix D: Updated to include "Delafloxacin belongs to the fluoroquinolone class of antibacterial drugs and is anionic in nature…".	12/01/21
RxA.360.Copiktra	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Initial Approval Criteria, IA.4: Updated from "Relapsed/refractory disease after at least one prior therapy" to "Relapsed/refractory disease after at least two prior therapies…". Appendix D: Updated to include drug interaction information, "CYP3A inducers: Avoid co-administration with strong CYP3A inducers."	12/01/21
RxA.361.Cotellic	Initial Approval Criteria, I.A: Updated from "Melanoma" to "Metastatic or Unresectable Melanoma." Initial Approval Criteria, I.B: Updated to include off-label indication, "Central Nervous System (CNS) Cancers (off -label)." Initial Approval Criteria, I.C: Updated to include off-label indication, "Cutaneous Melanoma (off-label)."	12/01/21

	Initial Approval Criteria, I.D: Updated to include off-label indication, “Histiocytic Neoplasms - Langerhans Cell Histiocytosis (off -label).” Initial Approval Criteria, I.E: Updated to include off-label indication, “Histiocytic Neoplasms- Erdheim-Chester Disease (off -label).” Initial Approval Criteria, I.F: Updated to include off-0lable indication, “Histiocytic Neoplasms - Rosai-Dorfman Disease (off -label).” Continued Therapy Approval Criteria, II.A: Updated from “Melanoma” to “All Indications in Section I.” Continued Therapy Approval Criteria, II.A.3.b: Updated to include, “Dose is within FDA maximum limit for any FDA-approved indication or is supported…”.. Appendix A: Updated to include abbreviations WHO, PXA, LCH, CNS, MAP, MAPK, ERK and ECD. Appendix D: Updated to include “Cobimetinib is a reversible inhibitor of mitogen-activated protein kinase…” and “Cobimetinib and vemurafenib target two different kinases in the RAS/RAF/MEK/ERK pathway…”.	
RxA.362.Doptelet	Dosing Information, Chronic Immune Thrombocytopenia (ITP): Updated to include, “and titrate to 40 mg/day.” Appendix B, Drug Name: Updated to remove “Carimune® NF” and “Gammagard® S/D.”	12/01/21
RxA.363.Eligard_LupanetaPack_LupronDepot_LupronDepot-Ped	Background: Updated to include “In combination with a norethindrone acetate for initial management…” Background: Updated to remove “recommended treatment is limited to one injection(3 months) for Lupron Depot® (3.75, 11.25)…” Dosing Information, Dosing Regimen: Updated to include “up to 6 months of therapy or in combination with daily 5 mg tablet of norethindrone acetate…” Dosing Information, Dosing Regimen: Updated to remove “Diagnostic: 20 mcg/kg or as needed…” Dosing information, Indication: Updated to remove “Breast cancer” and “Ovarian cancer.”	12/01/21

	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Initial Approval Criteria, B.6.b: Updated to include "Lupron Depot® (3.75 mg) in combination with a norethindrone acetate: 3.75 mg per month with 5 mg tablet of norethindrone acetate daily…" Initial Approval Criteria, I.D.5: Updated to remove "Diagnostic use: Leuprolide acetate: 20 mcg/kg or as needed…" Initial Approval Criteria, I.G: Updated to include "Head and Neck Cancers - Salivary Gland Tumors (off-label)…" Continued Therapy Approval Criteria, II.G: Updated to include "Head and Neck Cancers - Salivary Gland Tumors (off-label)…" Appendix C: Updated to include "The contraindications for norethindrone acetate also apply…" Appendix D, Warnings and Precautions: Updated to include "Loss of bone mineral density (BMD): Duration of treatment is limited by risk of bone mineral density…"	
RxA.364 .Emflaza	Appendix A: Updated to include abbreviation DMD and "Food and Drug Administration." Appendix C: Updated to include "in Emflaza®." Appendix D: Updated to include "Vaccination: Do not administer live or live attenuated vaccines…"	12/01/21
RxA.365. Empliciti	Dosing Information, Dosing Regimen: Updated to remove "Dexamethasone: 28 mg PO between 3 and 24 hours before Empliciti®…" Dosing Information, Dosing Regimen: Updated to include "Dexamethasone+ lenalidomide+ Empliciti®…" and "Dexamethasone+ pomalidomide+ Empliciti®…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix D: Updated to include "Infusion reactions. Premedication is required….".	12/01/21
RxA.366.Endari	Appendix A: Updated to include abbreviations SCD, RBC, NAD, NADH. Appendix B, Drug Name: Updated to remove Hydrea. Appendix D: Updated to include "Oxidative stress phenomena are involved in the pathophysiology of SCD…"	12/01/21
RxA.367.Crinone_Endometrin_ Prometrium	Appendix C, Boxed Warning: Updated to include "Prometrium®: Cardiovascular Disorders, Breast Cancer & Probable Dementia…"	12/01/21

RxA.370.Epidiolex	Background: Updated to include "…or tuberous sclerosis complex in patients 1 year of age and older". Dosing Information, Indication: Updated from "Dravet Syndrome & LennoxGastaut Syndrome" to "Seizures associated with Dravet Syndrome & Lennox-Gastaut Syndrome". Dosing Information, Dosing Regimen, Seizures Associated with Dravet Syndrome & Lennox-Gastaut Syndrome: Updated to include "Based on individual clinical response and tolerability, Epidiolex® can be increased…". Dosing Information, Indication: Updated to include "Seizures associated with tuberous sclerosis complex" and its respective dosing information and maximum dose. Initial Approval Criteria, I.A.3: Age criteria was updated from "Age ≥ 2 years" to "Age ≥ 1 years". Initial Approval Criteria, I.A.4: Updated to include "Obtain baseline complete blood count (CBC), serum transaminase and total bilirubin prior to initiating therapy". Initial Approval Criteria, I.A.4: Updated to remove "Will be used as adjunctive therapy (see Appendix B) with at least one other antiepileptic drug". Initial Approval Criteria, I.A.5: Updated to include generic drug names srufinamide and valproic acid. Initial Approval Criteria, I.A.6: Updated to include "For DS, failure of at least two of the following, unless contraindicated or clinically significant adverse…". Initial Approval Criteria, I.B: Updated to include indication "Tuberous sclerosis complex". Continued Therapy Approval Criteria, II.A: Updated from "Dravet Syndrome or Lennox-Gastaut Syndrome" to "All indications in section I". Continued Therapy Approval Criteria, II.A.3: Updated from "If request is for a dose increase, new dose does not exceed 10 mg/kg orally twice daily (20 mg/kg/day)" to "If request is for a dose increase, new dose does not exceed…". Continued Therapy Approval Criteria, II.A.3: Updated to include sub-criteria a and b; "10 mg/kg orally twice daily (20 mg/kg/day) for DS and LGS" and "12.5 mg/kg twice daily (25 mg/kg/day) for TSC"; respectively. Appendix A: Updated to include abbreviation TSC.	12/01/21

	Appendix D, General Infromation: Updated to remove definitions of Dravet Syndrome and Lennox-Gastaut Syndrome. Appendix D, General Information: Updated to include information regarding a. Hepatocellular Injury b. Somnolence and Sedation c. Suicidal Behavior and Ideation d. Hypersensitivity Reactions e. Withdrawal of Antiepileptic Drugs.	
RxA.374.Erbitux	Dosing Information, Dosing Regimen: Updated to include "Premedicate with an Ḥ receptor antagonist…" and "Complete Erbitux® administration 1 hour prior to radiation therapy…". Dosing Information maximum dose was updated to include "400 mg/ m^2 intravenously for the initial dose…". Initial Approval Criteria, I.A.5.a: Updated to include "OR 500 mg/ m^2 intravenously every 2 weeks". Initial Approval Criteria, I.B.6.a: Updated to include "OR 500 mg/ $m^{2"}$. Continued Therapy Approval Criteria, II.A.3.a: Updated to include "OR 500 mg/ $m^{2"}$.	12/01/21
RxA.376.Erleada	Initial Approval Criteria, I.A.1.a: Updated to include "progression (PSADT ≤ 10 months)." Appendix A: Updated to include abbreviation PSADT. Appendix B: Updated to include therapeutic alternative drugs Enzalutamide (Xtandi), Nubeqa (Darolutamide), and arbiraterone (Yonsa, Zytiga).	12/01/21
RxA.377.Erwinaze	Dosing Information, Dosing Regimen: Updated to include "To substitute for native E coli-derived asparaginase…" Dosage Forms: Updated from "per vial" to "single-dose vial for reconstitution…" Initial Approval Criteria, I.A.2.b: Updated to include "for the induction therapy in adults ≥ 65 years of age or with substantial comorbidities" Initial Approval Criteria, I.A.3 & I.A.2.b: Consolidated to form new criteria I.A.2, "Request meets one of the following (a or b):". Initial Approval Criteria, I.A: Updated to include the disclaimer "*Prescribed regimen must be FDA-approved or recommended by NCCN." Initial Approval Criteria and Continued Therapy Approval	12/01/21

	Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include NCCN. Appendix D, Warnings and Precautions: Updated to include information regarding a. Hypersensitivity Reactions b. Pancreatitis c. Glucose Intolerance d. Thrombosis e. Hemorrhage.	
RxA.378.Esbriet	Appendix A: Updated to include abbreviations ALT and AST. Appendix D: Updated to include " Esbriet® is not recommended for..." and "Photosensitivity and rash: Photosensitivity and rash have been…" Appendix D: Updated to include "Moderate (e.g., ciprofloxacin) and strong inhibitors of CYP1A2..."	12/01/21
RxA.380.Evenity	Initial Approval Criteria, I.A.2: Updated to include "Prescribed by orthopaedics". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21
RxA.385.Gazyva	Dosing Information, Dosing Regimen: Updated from " chlorambucil (0.5 mg/kg…" to" chlorambucil (0.5 mg/kg/day…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix D, General Information: Established to include " Gazyva® can cause fetal harm. Advise females of…".	12/01/21
RxA.387.Aloxi	Appendix B, Drug Names: Updated to remove discontinued brand Anzemet® and unavailable generic dolasetron.	12/01/21
RxA.388.Halaven	Initial Approval Criteria, I.A.5.b: Updated to include "Third-line therapy and beyond in combination with margetuximab-cmkb…". Initial Approval Criteria, I.A.6: Updated to include **"**For inflammatory breast cancer request should meet…" and I.A.6.a "As a single agent with no response to…" Initial Approval Criteria, I.B.1.c: Updated to include "Solitary Fibrous Tumor." Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21

RxA.389.Hemangeol	Dosing Information, Dosing Regimen: Updated to include "Note - Monitor heart rate and blood pressure for 2 hours after the first dose or increasing dose." Initial Approval Criteria, I.A.3: Updated to include "Prescribed by or in consultation with pediatric dermatologist."	12/01/21
RxA.390.Hetlioz	Clinical Policy, Drugs Applied: Updated to include "Hetlioz LQ™.". Background: Updated to include "Night-time sleep disturbances…" and "Hetlioz LQ™ oral suspension is indicated…". Dosing Information, Dosing Regimen, Hetlioz® and Hetlioz LQ™: Updated to include "Night-time sleep disturbances in Smith-Magenis Syndrome (SMS)…". Dosage Forms: Updated to include "Oral suspension: 4 mg/mL". Initial Approval Criteria, I.A.3: Updated to include "Member should be age ≥ 18 years …". Initial Approval Criteria, I.B: Updated to include new indication "Night-time sleep disturbances in Smith-Magenis Syndrome…". Continued Therapy Approval Criteria, II.A: Updated from "Non-24 Hour Sleep Wake Disorder" to "All Indications in Section I.". Appendix A: Updated to include abbreviation for SMS. Appendix D, General Information: Updated to include "Administer Hetlioz® capsules without food and if a patient …".	12/01/21
RxA.393.Imfinzi	Continued Therapy Criteria, Approval Duration: Updated from "up to but not exceed 12 months" to "12 months" for Commercial and Medicaid.	12/01/21
RxA.394.Injectafer	Dosing Information, Dosing Regimen: Updated to include "Alternatively, Injectafer® 15 mg/kg to a maximum of 1,000 mg…". Dosing Information, Maximum Dose: Updated to include "15 mg/kg/dose IV (Max: 1,000 mg/dose) when given as a single-dose…". Dosage Forms: Updated to include "1,000 mg iron/20 mL single-dose vial…". Initial Approval Criteria, I.A.2: Updated to include age criteria such that Age ≥ 18. Initial Approval Criteria, I.B.3: Updated to include age criteria such that Age ≥ 18.	12/01/21

	Continuation Therapy Approval Criteria, II.A.2: Updated to include “Member is responding positively to the therapy…”. Appendix A: Updated to include abbreviation FDA. Appendix D, General Information: Updated to include “Hypersensitivity Reactions: Observe for signs and symptoms…”	
RxA.396.Lonsurf	No Update	12/01/21
RxA.398.Lucentis	No Update	12/01/21
RxA.399.Lutathera	Dosing Information, Maximum Dose: Updated to include “7.4 GBq (200 mCi) Intravenously (Maximum cumulative dose of 29.6 GBq)…”. Initial Approval Criteria, I.A.3: Updated to include “Pregnancy status in females of reproductive potential…”. Initial Approval Criteria, I.B.5: Updated to include “Member experienced disease progression while on…”. Appendix A: Updated to include “GBq: Gigabecquerel.” Appendix D, General Information: Updated to include “For somatostatin receptor-positive bronchopulmonary/thymus…”, “Renal toxicity…”, and “Hepatotoxicity…”.	12/01/21
RxA.400.Lumoxiti	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B: Updated to include "Mavenclad" brand. Appendix C, Boxed Warnings: Updated to include “including life-threatening cases, occurred in patients…”.	12/01/21
RxA.401.Lynparza	Initial Approval Criteria, I.B.5: Updated to include “Patients with hormone receptor (HR)-positive breast cancer…”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B, Drug Name: Updated to remove inactive brand name ”Taxotere”. Appendix D: Updated to include "approximately 1.5% of patients…”.	12/01/21
RxA.402.Luxturna	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Initial Approval Criteria, I.A.2: Updated to include ”or retinal surgeon with experience providing sub-retinal injections…”.	12/01/21

	Appendix A: Updated to include FST, RPE65 and VA.	
RxA.403.Leucovorin_Injection	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviations CNS and AIDS.	12/01/21
RxA.405.Lidoderm_Ztlido	Clinical Policy, Drug(s) Applied: Updated from ZTlido™ to ZTlido®. Dosing Information, Indication: Updated to remove off-label "Diabetic neuropathy…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviation PHN. Appendix D, General information: Updated to include "Lidocaine toxicity can be expected at…".	12/01/21
RxA.407.Lorbrena	Background: Updated to remove "Lorbrena is indicated for the treatment of patients with ALK...". Dosing Information: Updated to include "Severe Renal Impairment(CrCl 15 to < 30 mL/min): 75 mg orally once daily". Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Initial Approval Criteria, I.A.5.a: Updated to include "As a single agent preferred first line therapy…". Initial Approval Criteria, I.A.6: Updated to include Rozlytrek. Initial Approval Criteria, I.B: Updated to include off-label indication, "CNS Cancer (Limited & Extensive Brain Metastases) (Off -Label)…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Criteria, II.A: Updated to "All Indications in Section I.". Appendix D, General Information: Updated to include "Risk of Serious Hepatotoxicity with Concomitant Use of Strong CYP3A Inducers…".	12/01/21
RxA.410.Lucemyra	Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Continued Therapy Approval Criteria, II.A.1: Rephrased to "	12/01/21

	Member is currently receiving the medication that has been authorized by..." Therapeutic alternative verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance..". Appendix B, Drug Name: Updated to remove Catapres®. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". Appendix D, General Information: Updated to include information regarding Risk of Hypotension, Bradycardia, and Syncope.	
RxA.412.Myobloc	Background: Updated to remove “Myobloc is an acetylcholine release inhibitor and a neuromuscular blocking agent.”. Dosing Information, Maximum Dose, Chronic Sialorrhea: Updated from “5000 units/12 weeks” to “3500 Units/12 weeks”. Initial Approval Criteria, I.A.3: Updated to remove “Member has a prior history of tolerating botulinum toxin injection…”. Initial Approval Criteria, I.A.6: Updated to include “Member meets both of the following (a and b)…”. Appendix D: Updated to include “Spread of toxin effects; swallowing and breathing difficulties…”, “Myobloc® potency units cannot be compared to or converted…”, and “Patients with neuromuscular disorders should be monitored…”.	12/01/21
RxA.414.Nubeqa	Dosing Information, Dosing Regimen: Updated to include “For severe renal and hepatic impairment recommended dose is 300 mg twice daily”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria, I.A.4: Updated to remove option allowing Nubeqa to be used as monotherapy. Appendix D: Updated to include “Embryo-Fetal Toxicity: Nubeqa® can cause fetal harm...”.	12/01/21
RxA.415.Nulojix	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B, Drug Name: Updated to include therapeutic alternative cyclosporine (Gengraf®, Neoral®, Sandimmune®).	12/01/21

RxA.416.Nuvigil	Dosing Information, Footnote: Updated to include "*Recommendation of reduced dose in severe hepatic impairment patient due to decreased clearance and increased steady-state concentration…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving the medication that has been authorized by RxAdvance..." Appendix D, Warnings and Precautions: Updated to include "Serious Rash, including Stevens-Johnson Syndrome: discontinue Nuvigil®…"	12/01/21
RxA.417.Nayzilam	Appendix C, Boxed Warning: Updated to include "The use of benzodiazepines, including Nayzilam® , exposes users…".	12/01/21
RxA.418.Ninlaro	Initial Approval Criteria, I.A.4: Updated to include "with multiple myeloma who have received at least one prior therapy…". Initial Approval Criteria, I.A.5: Updated to include "Primary therapy for symptomatic multiple myeloma or for disease…". Initial Approval Criteria, I.A.6: Updated to include "Therapy for previously treated multiple myeloma for relapse or progressive disease…". Initial Approval Criteria, I.B.4: Updated to include "Prescribed as single agent or in combination with dexamethasone…". Initial Approval Criteria, I.C: Updated to include off-label indication, "Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma (off-label)…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix D: Updated to include "Strong CYP3A inducers: Avoid concomitant use with Ninlaro®…".	12/01/21
RxA.420.Northera	No Update	12/01/21
RxA.421.Nuplazid	Initial Approval Criteria, I.A.4: Updated to include "with multiple myeloma who have received at least one prior therapy…". Initial Approval Criteria, I.A.5: Updated to include "Primary therapy for symptomatic multiple myeloma or for disease…". Initial Approval Criteria, I.A.6: Updated to include "Therapy for previously treated multiple myeloma for relapse or progressive disease…".	12/01/21

	Initial Approval Criteria, I.B.4: Updated to include "Prescribed as single agent or in combination with dexamethasone…". Initial Approval Criteria, I.C: Updated to include off-label indication, "Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma (off-label)…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix D: Updated to include "Strong CYP3A inducers: Avoid concomitant use with Ninlaro®…"	
RxA.422.Nuzyra	Dosing Information, Dosing Regimen, CAPB: Updated to include oral dosing "300 mg orally twice daily.". Initial Approval Criteria, I.A.2: Updated to include "Prescribed by, or in consultation with, an infectious disease specialist…". Appendix D, Warnings and Precautions: Updated to include "Mortality Imbalance in Patients with CABP…", "Tooth Discoloration and Enamel Hypoplasia…", "Inhibition of Bone Growth…", and "*Clostridioides difficile*-associated diarrhea…".	12/01/21
RxA.424.Odactra	Continued Therapy Approval Criteria, II.A.1: Updated to include "Diagnosis of HDM-induced allergic rhinitis…". Appendix A: Updated to include abbreviation IgE. Appendix D: Updated to include "Diagnosis of HDM-induced allergic rhinitis; Inform patients…" and "In case of oral inflammation or wounds, stop treatment with Odactra…".	12/01/21
RxA.428.Oncaspar	Initial Approval Criteria, I.B: Updated to include "nasal type…". Initial Approval Criteria, I.B.4.d: Updated to include "DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase)…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviations IU, IM, and IV. Appendix B: Updated to remove all prior therapeutic alternatives and to include "Not applicable." Appendix D, Warnings and Precautions: Updated to include "Anaphylaxis or serious hypersensitivity reactions…".	12/01/21
RxA.429.Onfi_Sympazan	Dosing Information, Dosing Regimen: Updated to include mild to moderate hepatic dosing information. Dosing Information, Indication: Updated to remove off label	12/01/21

	indications Intractable/refractory epilepsy and Dravet Syndrome. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviation CNS. Appendix B, Dosing Regimen and Maximum Dose: Updated to include specific information regarding a. Clonazepam b. Diazepam c. Vigabatrin d. Tiagabine e. Phenytoin f. Celontin g. Valproic Acid h. Vycompa i. Ethosuximide Appendix B, Drug Name: Updated to remove inactive/unavailable drugs a. Peganone b. Depakene c. Potiga d. Ethotoin e. Perampanel f. Brivaracetam g. Eslicarbazepine h. Ezogabine i. Lacosamide j. rufinamide k. methsuximide. Appendix C, Boxed Warnings: Updated to include indortmation regarding a. Onfi® and Sympazan b. The use of benzodiazepines, including Onfi®, exposes users to risks of abuse c. Abrupt discontinuation or rapid dosage reduction of Onfi® after continued use. Appendix D, Warnings and Precautions: Updated to include information regarding a. Somnolence or Sedation b. Withdrawal c. Serious Dermatological Reactions (including Stevens-Johnson Syndrome and toxic epidermal necrolysis) d. Physical and Psychological Dependence e. Suicidal Behavior and Ideation.	

RxA.430.Onivyde	Initial Approval Criteria, I.A.3: Updated to include prescriber criteria “Prescribed by or in consultation with an oncologist.”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviations ILD and HCL. Appendix C, Boxed Warnings: Updated to include "Fatal neutropenic sepsis…” and “Severe diarrhea...”. Appendix D, Warnings and Precautions: Updated to include “Interstitial lung disease….”, “Severe hypersensitivity reaction…”, and “Embryo-fetal toxicity…”.	12/01/21
RxA.431.Opdivo	Background: Updated to remove indications BRAF V600 melanoma and Small cell lung cancer (SCLC). Background: Updated to include new indications a. Melanoma b. Non-small cell lung cancer (NSCLC) c. Renal cell carcinoma (RCC) d. Squamous cell carcinoma of the head and neck (SCCHN) e. Urothelial carcinoma f. Colorectal cancer g. Hepatocellular carcinoma (HCC) h. Esophageal cancer i. Malignant pleural mesothelioma. Dosing Information, Indication: Updated to include Malignant Pleural Mesothelioma, GC, GEJC, and EACas well as their respective dosing regimen and maximum dose information. Initial Approval Criteria, Approval Duration: Updated to remove HIM. Initial Approval Criteria, I.C: Updated to remove indication, Small Cell Lung Cancer. Initial Approval Criteria, I.C.4 and I.C.4.a-c: Updated to include requirements for various therapies, including a. combination with ipilimumab, for the first-line treatment b. combination with cabozantinib, for the first-line treatment c. as a single agent Initial Approval Criteria, I.D.4.a-b: Updated diagnostic criteria Autologous Hematopoietic Stem Cell Transplantation to include combination with brentuximab vedotin.	12/01/21

	Initial Approval Criteria, I.D.4.b: Updated to include criteria that requires member to try 3 or more lines of systemic therapy that includes autologous HSCT. Initial Approval Criteria, I.G.2: Updated to include prescriber criteria. Initial Approval Criteria, I.G.3: Updated to include diagnostic criteria stating that member's tumor has progressed following treatment. Initial Approval Criteria, I.G.6.a: Updated to include additional dosage criteria indicating 240 mg every 2 weeks. Initial Approval Criteria, I.H.4: Updated to include generic drug name sorafenib. Initial Approval Criteria, I.J: Updated to include new indication Malignant Pleural Mesothelioma. Initial Approval Criteria, I.K: Updated to include new indication Gastic Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma. Initial Approval Criteria, I.L.1.g: Updated to include off-label indication, Uterine Neoplasms - Endometrial Carcinoma. Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Appendix A: Updated to a. Remove abbreviations BRAF and FDA b. Include abbreviations GC, GEJC, and EAC. Appendix B, Drug Name: Updated to a. Remove inactive drugs sorafenib and lomustine b. Include drugs Cotellic, Gilotrif, Afinitor, Gleostine, and Alimta. Appendix D, Warnings and Precautions: Updated to include a. The safety and effectiveness of Opdivo i. In pediatric patients <12 years old with MSI-H ii. In pediatric patients less than 18 years old b. Immune-mediated adverse reactions, which may be severe or fatal, can occur…".	

RxA.433.Opsumit	Initial Approval Criteria, I.A.2: Updated to remove “Member has documented proof of negative pregnancy test…”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviations WHO,PAH, and PH. Appendix B, Drug Name: Updated to remove brand-name drugs Afeditab CR, Procardia, and Dilacor XR. Appendix B, Dosing Regimen, Amlodipine: Updated from “20 to 30 mg PO once daily” to “Initial: 2.5 mg orally once daily; increase cautiously and progressively up to the maximum tolerated dose…”. Appendix B, Dosing Regimen and Maximum Dose, Diltiazem: Updated from “720 to 960mg” to “240 to 720mg.” Appendix D: Updated to include “Obtain a pregnancy test in females of reproductive potential prior…”	12/01/21
RxA.435.Orkambi	Dosing Information, Dosing Regimen: Updated to include “Hepatic Impairment: Reduce dose in patients with moderate…” and “Initiating Orkambi® in patients taking strong CYP3A inhibitors…”. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving medication that has been authorized by RxAdvance...". Appendix B, Drug Name: Updated to include alternative drugs aztreonam (Azactam®), tobramycin (Bethkis®), Symdeko®, and Pulmozyme®.	12/01/21
RxA.437.Oxaydo	Clinical Policy, Drugs Applied: Updated to remove unavailable brand-name drug Roxybond. Doing Information, Dosing Regimen: Updated to include “Conservative initial dose and dose titration are required…”. Dosing Information, Dosing Regimen: Updated to remove brand-name Roxybond.	12/01/21

	Dosage Forms: Updated to remove brand-name Roxybond. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Appendix A: Updated to include abbreviations PI and CDC. Appendix C: Updated to remove Roxybond. Appendix D: Updated to remove Roxybond.	
RxA.438.Oxervate	No Update	12/01/21
RxA.440.Ofev	Dosing Information, Dosing Regimen: Updated to include “Not recommended in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment….” Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. Initial Approval Criteria, I.C.7: Updated to include “Dose does not exceed 300 mg per day…”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21
RxA.442.Panhematin	Background: Updated to remove “is an enzyme inhibitor derived from processed red blood cells.” Dosage Forms: Updated to include "hemin, 240 mg sodium carbonate and 335 mg of sorbitol." Appendix A: Updated to include abbreviations ALA and UPG.	12/01/21
RxA.443.Parsabiv	Initial Approval Criteria, I.A.1: Updated from “hyperparathyroidism associated with CKD” to “hyperparathyroidism with CKD.” Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21
RxA.449.Prevymis	Clinical Policy statement was updated ‘‘The provision of provider samples does not guarantee coverage…”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include abbreviations HCT, CLCr and DNA. Appendix D: Updated to include “Hepatic Impairment…” and “Renal Impairment…”.	12/01/21

RxA.450.Provenge	Dosing Information, Maximum Dose: Updated to include “50 million autologous CD54+ cells activated…”. Initial Approval Criteria, I.A.4: Updated to include “Member meets one of the following (a or b)…” Initial Approval Criteria, I.A.4.a and I.A.4.a.i-ii: Updated to include criteria indicating a. Member has not received Provenge® previously b. Member is asymptomatic c. Member is symptomatic Initial Approval Criteria, I.A.4.b and I.A.4.b.i-iii: Updated to include criteria indicating a. Member has received Provenge® previously b. Member is asymptomatic c. Prior docetaxel and no prior novel hormone therapy d. Prior novel hormone therapy and no prior docetaxel. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to remove abbreviation FDA. Appendix A: Updated to include abbreviations ECOG and LHRH. Appendix D: Updated to include “Examples of novel hormone therapy includes: Yonsa (arbiraterone), Zytiga (arbiraterone), Xtandi (enzalutamide)…” and “Eastern Cooperative Oncology Group (ECOG) performance status (0-4)…”	12/01/21
RxA.451.Pulmozyme	Initial Approval Criteria, I.A.2: Updated to include “Prescribed by or in consultation with pulmonologist and gastroenterologist…”. Appendix A: Updated to remove abbreviation FDA.	12/01/21
RxA.452.Panretin	Dosing Information, Dosing Regimen: Updated to include “…based on individual lesion tolerance”. Initial Approval Criteria, I.A.8: Updated to include “Application does not exceed 4 applications topically per lesion/day”. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Continued Therapy Approval Criteria, II.A.5: Updated to include “Application does not exceed 4 applications per lesion/day”. Appendix A: Updated to include abbreviations HIV and ART.	12/01/21

RxA.453.Portrazza	Dosing Information, Maximum Dose: Updated from “800 mg per infusion” to “800 mg intravenously on Days 1 and 8”. Dosage Forms: Updated from “Single-dose vial: 800 mg/50 mL (16 mg/mL)” to “Injection: 800 mg/50 mL (16 mg/mL) solution in a single-dose vial”. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21
RxA.454.Praluent	Background: Updated to include new indication Homozygous familial hypercholesterolemia (HoFH) as an adjunct to other LDL-C-lowering therapies. Dosing Information, Dosing Regimen: Updated to include new indication Adults with HoFH. Initial Approval Criteria, I.B: Updated to include a new indication, Homozygous familial hypercholesterolemia (HoFH), in addition to its corresponding approval criteria. Continued Therapy Approval Criteria, II.A: Updated from “Primary Hyperlipidaemia (including HeFH) and Atherosclerotic Cardiovascular Disease” to “All Indications in Section I.” Continued Therapy Approval Criteria, II.A.2: Updated to include “Member is responding positively to the therapy;”. Initial approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix C, Contraindications: Updated from “History of serious hypersensitivity reaction to Praluent” to “History of serious hypersensitivity reaction to alirocumab or any of the excipients in Praluent.” Appendix F: Table was updated to include drug name Lomitapide and its respective contraindications.	12/01/21
RxA.457.Promacta	Background: Updated to remove indication “Myelodysplatic Syndromes (MDS) with severe Thrombocytopenia”. Background: Updated to include Limitation(s) of Use “Promacta® is not indicated for the treatment of patients with myelodysplastic syndrome (MDS).”. Dosing Information, Dosing Regimen: Updated to include hepatic impairment dosing for indication Chronic ITP, “For patients with ITP and mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, C)…” and “For patients of Asian ancestry with ITP and hepatic impairment (Child-Pugh Class A, B, C)…”.	12/01/21

	Dosing Information, Refractory Severe Aplastic Anemia: Updated to include “first-line severe aplastic anemia.” Dosing Information, Maximum Dose, Refractory Severe Aplastic Anemia and First-Line Severe Aplastic Anemia: Updated to include “Patients 12 years and older: 150 mg orally once daily; Patients 6 to 11 years: 75 mg…”. Dosing Information, Dosing Regimen, Refractory Severe Aplastic Anemia and First-Line Severe Aplastic Anemia: Updated to include “Dosage Regimen for Patients of Asian Ancestry or Those with Mild, Moderate, or Severe Hepatic Impairment (Child-Pugh Class A, B, C) in the First-Line Treatment of Severe Aplastic Anemia…”. Dosing Information, Indication: Updated to remove “Myelodysplatic Syndromes (MDS) with severe Thrombocytopenia” and its subsequent dosing regimen and maximum dose. Initial approval Criteria, I.C.4: Updated to include “…as the first line or refractory treatment;”. Initial Approval Criteria, I.C.5: Updated to remove “Member with Mild, Moderate, or Severe Hepatric Impairment…”. Initial Approval Criteria, I.C.6: Updated to include recommended dose for “ Severe aplastic anemia: Member is 12 years and older: 150 mg orally once daily; Member is 6 to 11 years: 75 mg orally once daily;..”. Initial Approval Criteria, I.D: Updated to remove indication , “Myelodysplatic Syndromes (MDS) with severe Thrombocytopenia.” Continued Therapy Approval Criteria, II.A.4: Updated to remove “Member with Mild, Moderate, or Severe Hepatic Impairment…”. Continued Therapy Approval Criteria II.A.5.d was updated to remove indication “Myelodysplatic Syndromes (MDS) with severe Thrombocytopenia.” Continued Therapy Approval Criteria, II.A.5.c: Updated to include “Severe aplastic anemia: Member is 12 years and older: 150 mg orally once daily; Member is 6 to 11 years: 75 mg orally once daily; Member is 2 to 5 years: 2.5 mg/kg orally once daily…”. Appendix A: Updated to remove abbreviation MDS.	

	Appendix B, Drug Name: Updated to include drugs “Active Injection D, Decadron®, Dexabliss, Dexamethasone Intensol, DoubleDex, Hemady, HiDex, MAS Care-Pak, ReadySharp Dexamethasone, TaperDex, ZCORT”, “DEPO-Medrol®, Medrol®, SOLU-Medrol”, and “predniSONE Intensol™, Rayos”. Appendix B, Drug Name: Updated to remove unavailable/inactive drugs Carimune NF and Gammagard.	
RxA.460.Request_for_Medically_Necessary_Drug_Not_on_the_PDL	No Update	12/01/21
RxA.463.Rubraca	Continued Therapy Approval Criteria, II.B.3: Updated to include “Continue androgen deprivation therapy (ADT) to maintain castrate levels…”. Appendix A: Updated to include abbreviations ADT, MDS, and AML. Appendix B, Drug Name: Updated to remove unavailable drug pemetrexed. Appendix D, Warnings and Precautions: Updated to include “Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)…” and “Embryo-Fetal Toxicity…”.	12/01/21
RxA.464.Rytary	Dosing Information, Drug Name: Updated to include generic drug carbidopa and levodopa extended release capsules. Dosing Information, Dosing Regimen: Updated to remove "Initial dose based off of total current daily dose of levodopa in IR carbidopa/levodopa (frequency of dosing may be increased to a maximum of 5 times daily if needed and tolerated)”. Dosing Information: Updated to include "Please refer PI”. Appendix A: Updated include abbreviations IR and ER. Appendix C, Contraindications: Updated to include “Hypertension can occur if these drugs are used concurrently.” Appendix D: Updated to include “May cause falling asleep during…”, “Avoid sudden discontinuation or rapid dose reduction…”, “Cardiovascular Events…”, “Hallucinations/Psychosis…”, “Impulse Control Disorders…”, and “May cause or exacerbate dyskinesia…”.	12/01/21
RxA.523.Trikafta	Background: Updated from “12 years and older” to “6 years and older.” Background: Updated to remove “Elexacaftor and tezacaftor bind to different sites on the cystic fibrosis transmembrane conductance regulator (CFTR) protein…”, “Ivafcaftor potentiates	12/01/21

	the channel open probability…", and "the combined effect of elexacaftor, tezacaftor, and ivacaftor is increased quantity and function of…". Dosing Information, Dosing Regimen: Updated to include "Age 6 to less than 12 years weighing less than 30 kgs…", "Age 6 to less than 12 years weighing 30 kgs or more…", and "For Hepatic impairment: Moderate impairment (Child-Pugh Class B)…". Dosing Information, Maximum Dose: Updated to include "For 6 to less than 12 years weighing less than 30 kgs…" and "6 to less than 12 years weighing 30 kgs or more & 12 years and older…". Initial Approval Criteria, I.A.1: Updated to remove "…with genetic testing confirming the presence of two disease causing mutations in CFTR gene.". Initial Approval Criteria, I.A.2: Updated to include "Member has at least one of the following mutations in the CFTR gene (a or b)…". Initial Approval Criteria, I.A.2.a: Updated to include "At least one F508del mutation;". Initial Approval Criteria, I.A.2.b: Updated to include "A mutation that is responsive based on in vitro data (see appendix D)". Initial Approval Criteria, I.A.3: Updated from "Age ≥ 12 years" to "Age ≥ 6 years". Initial Approval Criteria, I.A.7.a: Updated to include "6 years to less than 12 years weighing less than 30 kgs: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 150 mg per day". Initial Approval Criteria, I.A.7.b: Updated to include "6 years to less than 12 years weighing 30 kgs or more & 12 years and older: elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg per day". Initial Approval Criteria, I.A.7: Updated to remove "Moderate hepatic impairment: elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 150 mg per day". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Continued Therapy Approval Criteria, II.A.2.a: Updated to include "Stabilization in ppFEV1 if baseline was ≥ 70% or increase in ppFEV1 if baseline was < 70%". Continued Therapy Approval Criteria, II.A.2.b: Updated to include "Increase in chloride transport ≥ 10% since baseline".	

	Continued Therapy Approval Criteria, II.A.4: Updated to include "dose does not exceed any of the following (a or b)…". Continued Therapy Approval Criteria, II.A.4.a: Updated to include "6 years to less than 12 years weighing less than 30 kgs…". Continued Therapy Approval Criteria, II.A.4.b: Updated to include "6 years to less than 12 years weighing 30 kgs or more & 12 years and older…". Appendix B, Drug Name: Updated to include alternatives Orkambi, Symdeko, and Kalydeco as well as their respective dosing regimens and dose limits. Appendix D: Updated to include "List of CFTR Gene Mutations that are Responsive to Trikafta®" and subsequent table.	
RxA.537.Vancocin	Clinical Policy Title: Updated from "vancomycin oral" to "vancomycin HCl." Background: Updated to include limitation of use "Parenteral administration of vancomycin is not effective…". Appendix A: Updated to include abbreviation CDAD. Appendix B: Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". Appendix B, Drug Name: Updated to remove generic bezlotoxumab. Appendix B, Drug Name: Updated to include brand-name Zinplava and Dificid as well as their respective dosing regimens and maximum doses.	12/01/21
RxA.587.Aimovig	Initial Approval Criteria, I.A.3: Updated to remove prescriber criteria. Initial Approval Criteria, I.A.4: Updated to include generic drug names "atenolol" and "nadolol". Initial Approval Criteria, I.A.5: Updated to include generic drug descriptor "botulinum product". Initial Approval Criteria, I.A.6: Updated to remove sub-criteria a and b, "70mg (1 injection) once monthly" and "140mg (1 injection) once monthly if medical justification is provided", respectively.	12/01/21

	Initial Approval Criteria, I.A.6: Updated from "Dose does not exceed one of the following (a or b)" to "Dose does not exceed 140 mg once monthly". Continued Therapy Approval Criteria, II.A.3: Updated to include generic drug descriptor "a botulinum product". Continued Therapy Approval Criteria, II.A.4: Updated to remove sub-criteria a and b, "70mg (1 injection) once monthly" and "140mg (1 injection) once monthly if medical justification is provided", respectively. Continued Therapy Approval Criteria, II.A.4: Updated from "If request is for a dose increase, new dose does not exceed one of the following (a or b)" to "If request is for a dose increase, new dose does not exceed 140 mg once monthly". Appendix B, Drug Name: Updated to remove inactive/unavailable drugs Inderal, Lopressor, Elavil, and Effexor. Appendix B, Drug Name: Updated to include drugs atenolol and nadolol. Appendix D: Updated to include "Hypersensitivity reactions: If a serious hypersensitivity reaction occurs…", "Constipation with serious complications: Serious complications…", and "Hypertension: New-onset or worsening of pre-existing…".	
RxA.632.Dojolvi	Initial Approval Criteria, I.A.2: was updated to include "Prescribed by or in consultation with a metabolic disease specialist…". Continued Therapy Approval Criteria, II.A.3: Updated to include "Target daily dosage does not exceed 35%...". Appendix D, Warnings and Precautions: Updated to include "Feeding Tube Dysfunction…" and "Intestinal Malabsorption in Patients with Pancreatic Insufficiency…".	12/01/21
RxA.633.Isturisa	Background: Updated to include generic drug name osilodrostat. Dosing Information, Dosing Regimen: Updated to include hepatic impairment dosing "Adult Mild impairment (Child-Pugh class A): No dosage…". Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Initial Approval Criteria, I.A.4: Updated to include "Hypokalemia and hypomagnesemia levels are corrected, and baseline electrocardiogram is obtained prior to starting therapy…".	12/01/21

	Appendix A: Updated to include abbreviation FDA. Appendix D, Warnings and Precautions: Updated to include "Hypocortisolism…", "QTc Prolongation…", and "Elevations in Adrenal Hormone Precursors and Androgens…".	
RxA.634.Trodelvy	Background: Updated to include "Unresectable locally advanced or…", "Locally advanced or metastatic urothelial cancer (mUC)...", and "This indication is approved under accelerated approval based on tumor response…". Dosing Information, Indication: Updated to include "Locally advanced or metastatic urothelial cancer (mUC)…" and its respective dosing regimen and maximum dose information. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Initial Approval Criteria, I.B: Updated to include new indication "Bladder/Urothelial Cancer". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated from "8 weeks" to "56 days" for all indications. Continued Therapy Approval Criteria, II.B: Updated to include new indication "Bladder/Urothelial Cancer". Appendix A: Updated to include abbreviations mUC, PD-1, PDL1 and GU. Appendix B, Drug Name: Updated to include brand-name drug "Padcev®" and its respective daily dose and maximum dose. Appendix B, Drug Name: Updated to remove generic drug "atezolizumab" as it is only available in brand form. Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name®...". Appendix B, Dosing Regimen, epirubicin (Ellence®)"and cyclophosphamide IV: Updated from cyclophosphamide 500 mg^2 to "400 mg^2" and fluorouracil 400 mg^2 to "500 mg^2"; also updated from "depending on patient recovery" to "for 6 to 9 cycles". Appendix B, Drug Name: Updated to remove discontinued brand	12/01/21

	name Adrucil for fluorouracil . Appendix D: Updated to include “Do not substitute Trodelvy®”.	
RxA.635.Pemazyre	Clinical Policy Title: Updated to include Last Review Date. Dosing Information, Indication: Updated to include “Unresectable locally advanced or metastatic cholangiocarcinoma”. Dosing Information, Dosing Regimen: Updated to include renal and hepatic impairment dosing “Severe renal impairment and Hepatic Impairment: 9 mg orally once daily…”. Initial Approval Criteria, I.A.6: Updated to include “Maximum dose does not exceed 13.5 mg/day”. Initial Approval Criteria, I.B: Updated to include off-label indication “Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene (off-label)”. Continued Therapy Approval Criteria, II.A.3: Updated to include “Maximum dose does not exceed (a or b)…”. Continued Therapy Approval Criteria, II.A.3.a: Updated to include “Cholangiocarcinoma: 13.5 mg/day”. Continued Therapy Approval Criteria, II.A.3.b: Updated to include “Myeloid/Lymphoid Neoplasms: Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)”. Appendix A: Updated to include abbreviations NCCN, ALL, AML, HCT, OCT, and PFS. Appendix D, General Information: Updated to include “Ocular Toxicity: Pemazyre® can cause retinal pigment epithelial detachment…”, “Hyperphosphatemia and Soft Tissue Mineralization: Pemazyre® can cause hyperphosphatemia…”, “Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients…”, “Renal impairment (severe, estimated GFR 15 to 29 mL/min/1.73 m(2), estimated…”, and “Hepatic impairment (severe, total bilirubin greater than 3x ULN with any AST)”.	12/01/21
RxA.638.DarzalexFaspro	Background: Updated to include new indications, “In combination with bortezomib, thalidomide, and dexamethasone…” and “Light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone…”. Background: Updated to include Limitations of Use, “Darzalex	12/01/21

	Faspro® is not indicated and is not recommended for the treatment of patients…". Dosing Information, Maximum Dose, daratumumab and hyaluronidase: Updated to include "1,800 mg daratumumab and 30,000 units hyaluronidase (15 mL) subcutaneously once weekly." Dosing Information, Dosing Regimen, daratumumab and hyaluronidase: Updated to include "In combination with bortezomib, thalidomide, and dexamethasone…" for indication multiple myeloma. Dosing Information, Indication: Updated to include "Systemic Light Chain Amyloidosis…" and its respective dosing regimen/maximum dose. Initial Approval Criteria, I.A.4.b.ii: Updated from "As monotherapy or in combination with pomalidomide and dexamethasone after ≥ 2 prior therapies" to "As monotherapy in patients who have received at least three prior line therapies." Initial Approval Criteria, I.B: Updated to include new indication "Systemic Light Chain Amyloidosis...". Continued Therapy Approval Criteria, II.A: Updated from "Multiple Myeloma" to "All Indications in Section I." Appendix B: All dose limits in the table were updated from "See full product information for details" to their respective specific dose limits (ie/1.3 mg/m^2 per dose intravenously or subcutaneously; 1.6 mg/m^2 per dose intravenously…").	
RxA.639.Phesgo	Dosing Information: primary indication was updated from "Breast Cancer (Initial dose)" to "Breast Cancer (Neoadjuvant)". Dosing information: Secondary indication was updated from "Breast Cancer (Neoadjuvant & Adjuvant)" to "Breast Cancer (Adjuvant)". Dosing Information, Breast Cancer (Neoadjuvant): Updated to include "Administer 3-6 cycles for early breast cancer" and "followed by maintenance dosing 3 weeks later; Maintenance Dose:". Dosing Information, Breast Cancer (Adjuvant): Updated to include "Initial dose: 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase administered subcutaneous followed by maintenance…". Dosing Information, Metastatic Breast Cancer: Updated to	12/01/21

	include “Initial loading dose: pertuzumab 1,200 mg/trastuzumab 600 mg/hyaluronidase 30,000 units initially, followed 3 weeks later by maintenance dosing. Maintenance dosing…”. Dosing Information, Maximum Dose: Updated from “600mg every 3 weeks” to “1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase subcutaneous/dose…”. Initial Approval Criteria, I.A: Updated from “Breast Cancer” to “HER-2 positive Breast Cancer (must meet all)…” Appendix A: Updated to remove abbreviation FDA. Appendix B, Drug Name: Updated to remove inactive/unavailable drugs pertuzumab, trastuzumab, trastuzumab dkst, trastuzumab dttb, trastuzumab pkrb, trastuzumab qyyp, trastuzumab anns, and trastuzumab hyaluronidase oysk.	
RxA.640.Sarclisa	Background: Updated to include “In combination with carfilzomib and dexamethasone, for the treatment of adult patients…”. Dosing Information, Indication: Updated to include “Progressive Multiple myeloma or RRMM”. Dosing Information, Dosing Regimen: Updated to include “In combination with pomalidomide and dexamethasone for progressive Multiple myeloma OR carfilzomib and dexamethasone for RRMM;”, “…(in combination with pomalidomide and dexamethasone or in combination with carfizomib and dexamethasone)…”, and “…(in combination with pomalidomide and dexamethasone or in combination with carfizomib and dexamethasone)…”. Dosing Regimen, Maximum Dose: Updated from “No max dose” to “10mg/kg”. Initial Approval Criteria, I.A.1: Updated to include “…relapsed, refractory, or progressive…”. Initial Approval Criteria, I.A.4.a: Updated to include new criteria for indication multiple myeloma such that Sarclisa is prescribed in combination with pomalidomide and dexamethasone. Initial Approval Criteria, I.A.4.b: Updated to include new criteria for indication relapsed or refractory multiple myeloma such that Sarclisa is prescribed in combination carfilzomib and dexamethasone.	12/01/21

	Continued Therapy Approval Criteria, II.A: Updated from "All Indications in Section I" to "Multiple Myeloma". Appendix A: Updated to include abbreviations FDA, NCCN, and RRMM. Appendix B, Drug Name: Updated to include brand-name drug Kyprolis and its combination regimen. Appendix C, Contraindications: Updated to include "patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients…". Appendix D: Updated to include "Infusion-Related Reactions: In case of grade ≥ 2, interrupt Sarclisa® and manage medically….".	
RxA.641.Tabrecta	Clinical Policy Title: Updated remove brand "Tabrecta" for consistency. Clinical Policy Title, Line of Business Policy Applies to: Updated from "Commercial, Medicaid, Medicare" to "All lines of business". Dosing Information, Indication: Updated from "TABRECTA is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymalepithelial…" to "Metastatic NSCLC". Initial Approval Criteria, I.A.2: Updated to include prescriber criteria "Prescribed by or in consultation with an oncologist;". Initial Approval Criteria, I.A.5.a: Updated to include "Dose does not exceed 400 mg twice daily;". Initial Approval Criteria, I.A.5.b: Updated to include "Dose is supported by practice guidelines or peer-reviewed literature…". Initial Approval Criteria, I.B: Updated to include off-label indication "Central nervous system cancer (off- label)…". Continued Therapy Approval Criteria, II.A: Updated from "Non Small Cell Lung Cancer" to "All Indications in Section I (must meet all)…". Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Continued Therapy Approval Criteria, II.A.3: Updated to include "If request is for dose increase request meets one of the following (a or b)…".	12/01/21

	Continued Therapy Approval Criteria, II.A.3.a: Updated to include “New dose does not exceed 400mg twice daily;”. Continued Therapy Approval Criteria, II.A.3.b: Updated to include “New dose is supported by practice guidelines or peer-reviewed literature…”. Appendix B: Updated to remove statements, “Xalkori (crizotinib) inhibits ALK fusions, ROS1 fusions and some MET tyrosine kinases (high-level MET amplification or METex14 mutation). It is approved by the FDA…”, “Tagrisso (osimertinib), although not FDA approved for patients with NSCLC with METex14 mutations…”, and “Cabometyx (cabozantinib), also not FDA approved for this type of NSCLC, has been studied…”. Appendix B, Drug Name: Updated to include brand-name drugs Xalkori and Tepmetko, as well as their respective dosing regimens and dose limits, in table format. Appendix D: Updated to include “ECOG Performance Status” and subsequent Grade 0-5 designations.	
RxA.642.Zepzelca	Background: Updated to include generic drug name Lurbinectedin. Initial Approval Criteria, I.A.4: Updated to include “Patient’s performance Score is 0-2…”. Initial Approval Criteria, I.A.6.b: Updated to remove “dose is supported by practice guidelines or peer-reviewed literature for the related off-label use…”. Continued Therapy Approval Criteria, II.A.2.b: Updated to remove “dose is supported by practice guidelines or peer-reviewed literature for the related off-label use…”. Appendix A: Updated to include abbreviations CNS and AUC. Appendix B, Drug Name: Updated to include alternative drugs Tecentriq, Imfinzi, and etoposide as well as their respective dosing regimens and maximum doses. Appendix D: Updated to include “Reference ranges for performance score…” and subsequent ECOG Performance Status reference table.	12/01/21
RxA.643.Pizensy	Dosing Information, Dosing Regimen: Updated to include “Reduce the dosage to 10 grams once daily for persistent loose stools. Administer oral medications at least 2 hours before or 2 hours after Pizensy™.”.	12/01/21

	Initial Approval Criteria, I.A.6: Updated to include "Maximum dose does not exceed 20 grams orally once daily.". Continued Therapy Approval Criteria, II.A.3: Updated to include "Maximum dose does not exceed 20 grams orally once daily.". Appendix B, Dosing Regimen, FiberCon: Updated from "1,000mg 1 to 4 times per day or as needed" to "1,250 mg calcium polycarbophil orally 1 to 4 times daily". Appendix B, Maximum Dose, FiberCon: Updated from "6,000mg/day" to "5,000 mg of calcium polycarbophil orally once daily". Appendix D: Updated to include "Lactitol exerts an osmotic effect, causing the influx of water into the small intestine leading to a laxative effect in the colon.".	
RxA.644.Barhemsys	Background: Updated to include generic drug name "amisulpride". Dosing Information, Maximum Dose, Prevention of Postoperative Nausea and Vomiting (PONV) Either Alone or in Combination with an Antiemetic of a Different Class: Updated from "10mg/dose" to "5mg/dose". Dosage Forms: Updated to include "…or 10 mg/4 mL (2.5 mg/mL)…". Initial Approval Criteria, I.A: Updated from "Post-operative nausea and/or vomiting (PONV)" to "Post-operative nausea and vomiting (PONV)". Initial Approval Criteria, I.A.3: Updated to include "Prescribed by or in consultation with a specialist;". Initial Approval Criteria, I.A.6: Updated to include "Request meets one of the following (a or b)…". Initial Approval Criteria, I.A.6.a: Updated to include "For prevention: Dose does not exceed 5 mg once;". Initial Approval Criteria, I.A.6.b: Updated to include "For treatment: Dose does not exceed 10 mg once;". Continued Therapy Approval Criteria, II.A: Updated from "Post-operative nausea and/or vomiting (PONV)" to "Post-operative nausea and vomiting (PONV)". Appendix D: Updated to include "QT Prolongation: Occurs in a dose- and concentration-dependent manner…".	12/01/21

RxA.645.Inqovi	Dosing Information, Dosing Regimen and Maximum Dose: Updated to remove “One (1) tablet”. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. Initial Approval Criteria, I.A.4: Updated to include “Maximum dose does not exceed 175 mg decitabine and 500 mg cedazuridine for 28 days.”. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Continued Therapy Approval Criteria, II.A.3: Updated to include “If request is for a dose increase, maximum dose does not exceed 175 mg decitabine and 500 mg cedazuridine for 28 days.”. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". Appendix B: Updated from bullet-list format to table format. Appendix B, Drug Name: Updated to remove non-indicated drug “Inrebic (fedratinib)”. Appendix B, Drug Name: Updated to include alternative drugs decitabine (Dacogen®) and azacitidine (Vidaza®) in addition to their respective dosing regimens and maximum doses. Appendix B, Dosing Regimen and Maximum Dose: Updated to include specific requirements for previously listed alternative drugs Jakafi®, imatinib (Gleevec®), and Reblozyl®. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". Appendix D: Updated to include “Myelosuppression: Fatal and serious myelosuppression…” and “Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients…”.	12/01/21
RxA.646.Qinlock	Dosing Information, Dosing Regimen: Updated to include “Avoid concomitant use of moderate CYP3A inducers during Qinlock treatment. If a moderate CYP3A inducer cannot be avoided, increase the Qinlock dosing frequency…”.	12/01/21

	Dosing Information, Maximum Dose: Updated to include “150 mg twice daily when co-administered with moderate CYP3A inducers”. Dosage Forms: Updated from table format to bullet-list format. Initial Approval Criteria, I.A.5: Updated to include “Member has an ECOG performance status of 0- 2”. Initial Approval Criteria, I.A.6: Updated to include “Dose does not exceed 150 mg orally once daily or 150 mg twice daily when co-administered with moderate CYP3A inducers”. Continued Therapy Approval Criteria, II.A: Updated from “All Indications in Section I” to “Advanced Gastrointestinal Stromal Tumor”. Continued Therapy Approval Criteria, II.A.3: Updated to include “If the request is for dose increase dose does not exceed 150 mg orally once daily or 150 mg twice daily when co-administered with moderate CYP3A inducers”. Appendix A: Updated to include abbreviation ECOG. Appendix B, Drug Name: Updated to remove inactive/unavailable drugs avapritinib, sunitinib, and regorafenib. Appendix D: Updated to include “ECOG Performance Status” and subsequent grading schedule. Appendix D: Updated to include “Examples of moderate CYP3A inducers include, bosentan, efavirenz, etravirine, phenobarbital, primidone”. Appendix D: Updated to remove table, “NCCN Guidelines Version 2.2020: Gastroinestinall Stromal Tumors”.	
RxA.647.Tukysa	Background: Updated to include generic drug name Tucatinib. Dosing Information, Dosing Regimen: Updated to include hepatic impairment dosing “Severe hepatic impairment (Child-Pugh class C): Reduce initial dose to 200 mg twice daily…”. Dosing Information, Dosing Regimen: Updated to include renal impairment dosing “Renal Impairment: CrCl <30 mL/minute: Use is not recommended…”. Initial Approval Criteria, I.A.1: Updated from “Diagnosis of recurrent, locally advanced, or metastatic breast cancer” to “Diagnosis of any one of the following (a or b)…”.	12/01/21

	Initial Approval Criteria, I.A.1.b: Updated to include “Brain metastases related to breast cancer…”. Initial Approval Criteria, I.A.2: Updated to include “Documentation of advanced, unresectable, or metastatic HER2-positive breast cancer…”. Initial Approval Criteria, I.A.4: Updated to remove “Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease…”. Initial Approval Criteria, I.A.5: Updated to include “Prescribed in combination with trastuzumab and capecitabine…”. Initial Approval Criteria, I.A.6: Updated to include “Member has received one or more prior anti-HER2-based regimens…”. Continued Therapy Approval Criteria, II.A.3.b: Updated to include “Dose is supported by practice guidelines or peer-reviewed…”. Appendix A: Updated to include abbreviations EBC, ALT, AST, NCCN & TDM1. Appendix B, Drug Name: Updated to include alternative drug Kadcyla and its dosing regimen and maximum dose. Appednix D: Updated to include “Embryo-Fetal Toxicity…” and “Hepatotoxicity…”.	
RxA.648.Uplinza	Appendix A: Updated to include abbreviations EDSS and AQP4. Appendix B, Drug Name: Updated to remove inactive generic drug teriflunomide.	12/01/21
RxA.650.Monjuvi	Background: Updated to remove “DLBCL is the most common subtype of non-Hodgkin lymphoma (NHL), accounting for approximately…” and “DLBCL is an aggressive NHL that typically presents as a rapidly enlarging mass in the lymph nodes in the neck…”. Dosing Information, Indication: Updated to remove “Treatment of adult patients with”. Initial Approval Criteria, I.A.5: Updated to include “Documentation supporting that the member is not eligible for autologous stem cell transplant (ASCT).”. Appendix A: Updated to include abbreviations CAR and NCCN.	12/01/21

	Appendix B, Drug Name: Updated to remove inactive/unavailable drugs polatuzumab vedotin piiq, tisagenlecleucel, axicabtagene ciloleucel, and selinexor. Appendix B, Maximum Dose, Polivy: Updated to include "1.8 mg/kg intravenous every 21 days". Appendix B, Dosing Regimen and Maximum Dose, Kymriah: Updated to include "0.6 to 6 X 108 CAR-positive viable T-cells infused as a single-dose" and "Adults ≥ 18 years: 6 X 108 CAR-positive viable T-cells". Appendix B, Dosing Regimen and Maximum Dose, Yescarta: Updated to "Target dose is 2 × 106 CAR-positive viable T cells per kg body weight intravenous" and "2 X 106 CAR-positive viable T-cells per kg of body weight (maximum dose of 2 X 108 CAR-positive viable T-cells) as a single intravenous dose". Appendix B, Dosing Regimen and Maximum Dose, Xpovio: Updated to include "Recommended dosage of Xpovio® is 60 mg orally on Days 1 and 3 of each week" and "60 mg orally twice weekly on days 1 and 3".	
RxA.651.Nexletol_ Nexlizet	Clinical Policy Title: Updated to include "bempedoic acid and ezetimibe" Background: Updated from "NEXLETOL/NEXLIZET is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous…" to "Bempedoic acid (Nexletol™)/ bempedoic acid and ezetimibe (Nexlizet™) both contains adenosine triphosphate-citrate lyase (ACL) inhibitor,w Nexletol™ contains a cholesterol absorption…". Background: Updated to include Limitations of Use, "Limitations of Use: The effect on cardiovascular morbidity and mortality has not been determined.". Dosing Information, Indication, Nexletol: Updated to remove "Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with". Dosing Information, Indication, Nexlizet: Updated to remove "Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with". Dosing Information, Dosing Regimen, Nexlizet: Updated from "180 mg once daily and 10 mg/day PO ezetimibe" to "180 mg bempedoic acid and 10 mg ezetimibe orally once daily with or without food".	12/01/21

	Dosing Information, Maximum Dose, Nexlizet: Updated from "bempedoic acid: 180 mg once daily" to "180 mg/day orally bempedoic acid and 10 mg/day orally ezetimibe". Initial Approval Criteria, I.A.3: Updated to include prescriber criteria, "Prescribed by or in consultation with a cardiologist, endocrinologist or lipidologist;". Initial Approval Criteria, I.A.5.a-b: Updated to include criteria such that member must meet one of the following a. If the request is for Nexletol™, dose does not exceed: 180 mg bempedoic acid b. If the request is for Nexlizet™, dose does not exceed: 180 mg of bempedoic acid/10 mg of ezetimibe. Initial Approval Criteria, I.B.1: Updated to include "Diagnosis of ASCVD;". Initial Approval Criteria, I.B.2: Updated to include age criteria, "Age ≥ 18 years;". Initial Approval Criteria, I.B.3: Updated to include prescriber criteria, "Prescribed by or in consultation with a cardiologist, endocrinologist or lipidologist;". Initial Approval Criteria, I.B.7: Updated to include "Request meets one of the following (a or b)…". Initial Approval Criteria, I.B.7.a: Updated to include "If the request is for Nexletol™, dose does not exceed: 180 mg bempedoic acid;". Initial Approval Criteria, I.B.7.b: Updated to include "If the request is for Nexlizet™, dose does not exceed: 180 mg of bempedoic acid/10 mg of ezetimibe.". Continued Therapy Approval Criteria, II.A.2: Updated to include "…(lab results showing LDL-C reduction since initiation of therapy);". Continued Therapy Approval Criteria, II.A.3: Updated from "Member continues to receive concomitant maximally tolerated statin therapy" to "If statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;". Continued Therapy Approval Criteria, II.A.4.a-b: Updated to include criteria such that member must meet one of the following a. If the request is for Nexletol™, dose does not exceed: 180 mg bempedoic acid	

	b. If the request is for Nexlizet™, dose does not exceed: 180 mg of bempedoic acid/10 mg of ezetimibe. Appendix B, Drug Name: Updated to include alternate drugs atorvastatin (Lipitor®), fluvastatin (Lescol XL ®), and lovastatin (Altoprev ®), in addition to their specific dosing regimens and maximum doses. Appendix C, Contraindications: Updated to include "Known hypersensitivity to ezetimibe tablets.". Appendix D, Warnings and Precautions: Updated to include "Hyperuricemia: Elevations in serum uric acid have occurred…" and "Tendon Rupture: Tendon rupture has occurred…"	
RxA.655.LA_Injectable_Antipsychotics	Dosing Information, Dosing Regimen, Abilify Maintena: Updated from " 200 to 400 mg every 4 weeks" to "160 mg-400 mg monthly (no sooner than 26 days after the previous injection)". Dosing Information, Maximum Dose, Aristada: Updated to include "Aristada Initio®: 675 mg one time dose". Dosing Information, Footnote: Updated to include "*Severe impairment (Child-Pugh class C) and Severe impairment (CrCl <30 mL/minute): 0.5 mg twice daily orally…" and "±Hepatic and Renal Impairment (Subcutaneous): Initiate with oral dosing…". Appendix D, Drug Name: Updated to remove inactive/unavailable drugs Thorazine, Prolixin, Loxitane, Trilafon, Orap, Mellaril, Navane, Stelazine, asenapine maleate, brexpiprazole, cariprazine, iloperidone, and lurasidone.	12/01/21
RxA.656.Artesunate	Appendix A: Updated to include abbreviations CDC and FDA. Appendix B, Maximum Dose, Coartem: Updated to include "8 tablets/day (total of 6 doses over 3 days)…" and dosing regimen for Coartem, "of 80 mg artemether/480 mg lumefantrine orally...". Appendix B: Updated to include "1000 mg atovaquone/400 mg proguanil hydrochloride orally once daily for 3 days…". Appendix B, Maximum Dose, Quinine Sulfate: Updated to include "1944 mg/day." Appendix B, Dosing Regimen, Mefloquine: Updated to include "1,250 mg orally as a single dose, or alternately, 750 mg orally as initial dose then 500 mg orally at 6 to 12 hours after initial dose…" and its respective maximum dose "1250 mg/day." Appendix B, Drug Name: Updated to include alternative drugs	12/01/21

	chloroquine, hydroxychloroquine, and primaquine in addition to their corresponding dosing information. Appendix B, Drug Name: Updated to remove unavailable drugs artemether-lumefantrine and Lariam.	
RxA.018.Aubagio	No Update	12/01/21
RxA.145.Gilenya	Initial Approval Criteria, I.A.4: Updated to remove "Trial and failure of at least two (2) preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Glatopa, F, Kesimpta,Ocrevus, Plegridy, or Zeposia".	12/01/21
RxA.146.Copaxone_Glatopa	Statement about provider sample "The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. Initial Approval Criteria, I.A.4: Updated to remove " Trial and failure of at least two (2) preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Glatopa, Kesimpta, Ocrevus, Plegridy, or Zeposia.". Appendix B, Dosing Information: Updated therapeutic alternatives to a. Include Aubagio, Avonex, Rebif, Plegridy, Betaseron, Extavia, Gilenya, Tecfidera, Mayzent, Zeposia, Bafiertam, Ponvory b. Remove Glatopa	12/01/21
RxA.151.Gilotrif	Dosing Information: Updated to include renal impairment dosing. Initial Approval Criteria, I.A.4.a: Updated to remove, "insertion; exon 21 point mutation L8618……S7681." Appendix B was rephrased to "Below are suggested therapeutic alternatives based on clinical…". Appendix D, General Information: Updated.	12/01/21
RxA.164.Ilaris	Dosage Forms: Updated. Appendix B, Drug Name: Updated to remove discontinued brand Rheumatrex.	12/01/21
RxA.173.Inrebic	Clinical Policy, Title: Updated to "fedratinib". Clinical Policy, Drug(s) Applied: Updated to "Inrebic®". Initial Approval Criteria, I.B: "Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (Off label)" was added and updated.	12/01/21

RxA.202.Lemtrada	Dosing Information: Updated from “Intravenous infusion for 2 or more…” to “Intravenous infusion over 4 hours for 2 or more…” Dosing Information, Indication: Updated to include “(relapsing-remitting disease and active secondary progressive disease)”. Initial Approval Criteria, I.A.4: Updated to include “(Avonex®, Betaseron®, Copaxone®, Vumerity®, Bafiertam®, Kesimpta®)”. Appendix A: Updated to include abbreviations CD52, CIS. Appendix B, Drug Name: Updated to remove unavailable drugs "interferon beta-1a, peginterferon beta-1a, Interferon Beta-1b, fingolimod, teriflunomide, siponimod". Appendix C, Contraindications: Updated to include “Active infection”. Appendix D, Drug Name: Updated to remove unavailable drugs " Lemtrada®” and “natalizumab, ocrelizumab, interferon beta-1a, interferon beta-1b, peginterferon beta-1a, monomethyl fumarate, diroximel fumarate, teriflunomide, fingolimod, siponimod, ozanimod”.	12/01/21
RxA.213.Mavenclad	Initial Approval Criteria, I.A.2: Updated from requiring member to try/fail 2 alternative therapies to requiring member to try/fail at least 1 alternative therapy; specific alternative drug names, “(Avonex®, Betaseron®,Copaxone®, Vumerity®, Bafiertam®, Kesimpta®)”.	12/01/21
RxA.215.Mayzent	Initial Approval Criteria, I.A.3: Updated to remove “Trial and failure of at least 2 preferred disease modifying therapies, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;”.	12/01/21
RxA.274.Avonex_Rebif	Initial Approval Criteria, I.A.5: Updated from requiring member to try/fail at least two alternative therapies in order to receive either Avonex or Rebif, to requiring member to try/fail at least two alternative therapies to obtain Rebif only. Appendix A: Updated to remove abbreviation SC.	12/01/21
RxA.350.Alimta	Initial Approval Criteria and Continued Therapy Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include NCCN. Appendix D, Warnings and Precautions: Updated to include “Myelosuppression: Can cause severe bone marrow suppression resulting in cytopenia…”	12/01/21
RxA.369.Epclusa	Dosing Information: Updated table to remove “References” column.	12/01/21

	Initial Approval Criteria, I.A.3: Updated to member to try generic "sofosbuvir-velpatasvir 400-100 mg tablets before brand Epclusa® 400-100 mg tablets". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration Footnote: Updated from "*Approved duration should be consistent with a regimen in Section V Dosage and Administartion" to "*Approved duration should be consistent with a regimen in Dosing Information section above"	
RxA.413.Mitoxantrone	Dosing Information, Dosing Regimen: Updated to include hepatic impairment dosing, "Patients with multiple sclerosis who have hepatic impairment..". Initial Approval Criteria, I.D.1: Updated to separate all subtypes of B-cell lymphoma. Initial Approval Criteria, I.D.2.a: Updated to include "Mitoxantrone used as third line or subsequent systemic therapy…". Initial Approval Criteria, I.D.2.b: Updated to include "Mitoxantrone used as second line and subsequent therapy as a component of MINE…". Initial Approval Criteria, I.D.2.c: Updated to include "Mitoxantrone used as a component of FMC…". Appendix C, Boxed Warning: Updated to include "Cardiotoxicity, secondary leukemia".	12/01/21
RxA.423.Ocrevus	Initial Approval Criteria, I.A.1.b: Updated to change from trial and failure of "two" alternative drugs to trial and failure of "at least one" alternative drug; list of acceptable drugs to try was updated from "Aubagio®, Tecfidera®, Gilenya®, Avonex®, Betaseron®, Plegridy®, glatiramer, Mayzent®, Copaxone®, Glatopa®, or Rebif®" to "Avonex®, Betaseron®, Copaxone®, Vumerity®, Bafiertam®, Kesimpta®". Initial Approval Criteria, I.A.6: Updated to include 'testing of quantitative serum immunoglobulin prior to initiating Ocrevus'. Continued Therapy Approval Criteria, Approval Duration: Updated from 6 months to 12 months. Appendix B, Drug Name: Updated to include "Zeposia", "Bafiertam" and "Ponvory".	12/01/21

RxA.432. Opioid Analgesics	Initial Approval Criteria, I.A, Approval Duration: Updated to "one time authorization per request". Appendix A: Updated to include abbreviation MED.	12/01/21
RxA.446.Plegridy	Initial Approval Criteria, I.A.4: Updated to include "Trial and failure of at least 2 preferred disease modifying therapies…". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM.	12/01/21
RxA.505.Tecfidera	Initial Approval Criteria, I.A.2: Updated from requiring member to try/fail at least two other therapies to requiring member to try/fail at least one other therapy; possible therapies to try were updated to include "(Avonex®, Betaseron®, Copaxone®, Vumerity®, Bafiertam®, Kesimpta®)". Initial Approval Criteria, I.A.4: Updated to include "Member..... dimethyl fumarate." Appendix A: Updated to remove abbreviations PO, IM, IV, and SC.	12/01/21
RxA.532.Tysabri	Initial Approval Criteria, I.A.4: Updated from requiring member to try/fail at least two other therapies to requiring member to try/fail at least one other therapy; possible therapies to try were updated to include "(Avonex®, Betaseron®, Copaxone®, Vumerity®, Bafiertam®, Kesimpta®)". Appendix A: Updated to remove abbreviations SC, PO, and IV.	12/01/21
RxA.636.Retevmo	Background: Updated to remove "Thyroid cancer is the most common type of endocrine cancer…". Background: Updated to include "This indication is approved under accelerated approval based on overall response rate and duration of response…" Dosing Information, Dosing Regimen: Updated to include hepatic impairment dosing "Severe hepatic impairment: Reduce the starting dose to 80 mg orally twice daily regardless of the original starting dose". Dosing Information, Maximum Dose: Updated from "160mg orally twice daily; 80mg orally twice daily;" to "<50kg: 240mg/day orally; ≥50kg: 320mg/day orally;". Dosing Information, Footnote: Updated to remove "*Severe hepatic impairment…". Initial Approval Criteria, I.A.5.a-b: Updated to include dosing information such that member must meet one of the following a. 240 mg per day for < 50 kg weight b. 320 mg per day for ≥ 50 kg weight.	12/01/21

	Initial Approval Criteria, I.B: Updated to include off-label indication “Histiocytic Neoplasms - Langerhans Cell Histiocytosis (off -label)…”. Initial Approval Criteria, I.C: Updated to include off-label indication “Histiocytic Neoplasms- Erdheim-Chester Disease (off -label)…”. Initial Approval Criteria, I.D: Updated to include off-label indication “Histiocytic Neoplasms - Rosai-Dorfman Disease (off -label)…”. Continued Therapy Approval Criteria, II.A: Updated from “Non-Small Cell Lung Cancer” to “Non-Small Cell Lung Cancer or Medullary Thyroid Cancer and other off label indications (must meet all)…”. Continued Therapy Criteria, II.A.4.a-b: Updated to include dosing information such that member must meet one of the following a. 240 mg per day for < 50 kg weight b. 320 mg per day for ≥ 50 kg weight. Continued Therapy Criteria, II.A.5: Updated to include “Dose is within FDA maximum limit for any FDA-approved indication…”. Appendix A: Updated to include abbreviations ALT, AST, and TSH. Appendix B, Indication: Updated to combine “RET-Positive NSCLC” and “RET-Positive Thyroid Cancer and Medullary Thyroid Cancer” into one category. Appendix B, Drug Name: Updated to remove Alcensa, alectinib, Caprelsa, vandetanib, Cometriq, cabozantinib S-malate, Lenvima, Lenvatinib, Nexavar, sorafenib, Sutent, and sunitinib. Appendix B: Updated to remove phrases “RET-Positive NSCLC: Alecensa (alectinib) has been tried, along with Caprelsa (vandetanib) and Cometriq (cabozantinib S-malate). None are FDA-approved for RET NSCLC” and “RET-Positive Thyroid Cancer and Medullary Thyroid Cancer: Caprelsa (vandetanib), Cometriq (cabozantinib Smalate), Lenvima (lenvatinib), and Nexavar (sorafenib) are used. Off label, Sutent (sunitinib) has been used”. Appendix B, Drug Names: Updated to include “Gavetro” and its respective dosing regimen and dose limit. Appendix D, Warnings and Precautions: Updated to include information regarding	

	a. Hepatotoxicity b. Severe hepatic impairment c. Hypertension d. QT Interval Prolongation e. Hemorrhagic Events f. Hypersensitivity g. Tumor Lysis Syndrome h. Risk of Impaired Wound Healing i. Embryo-Fetal Toxicity.	
RxA.649.Zeposia	Background: Updated to include new indication “Ulcerative colitis”. Dosing Information, Dosing Regimen and Maximum Dose: Updated to include new indication “Ulcerative colitis”. Dosage Forms: Updated from “Capsule: 0.23 mg, 0.46 mg, 0.92 mg.” to “Capsule: 0.23 mg, 0.46 mg, 0.92 mg ozanimod”. Initial Approval Criteria, I.A.4: Updated to remove “Trial and failure of at least 2 preferred disease modifying therapies, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;”. Initial Approval Criteria, 1.B: Updated to include a new indication, "Ulcerative colitis”. Appendix A: Updated to include abbreviations UC, RMS. Therapeutic alternative verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". Appendix B, Dosing Regimen and Maximum Dose: Updated to include specific info regarding listed drugs and to remove unavailable generic drugs natalizumab, ocrelizumab, alemtuzumab, interferon beta-1a, interferon beta-1b, peginterferon beta-1a, monomethyl fumarate, Teriflunomide, fingolimod, Siponimod and diroximel fumarate.	12/01/21
RxA.652.Betaseron	Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix A: Updated to include SPMS, CHF and TMA. Appendix B: Table was updated to include Dosing Regimen and Maximum Dose columns. Appendix B, Drug Name: Updated to remove inactive drugs “natalizumab, ocrelizumab, alemtuzumab , interferon beta-1a , interferon beta-1b, peginterferon beta-1a, monomethyl	12/01/21

	fumarate, diroximel fumarate" and "teriflunomide, fingolimod, siponimod, ozanimod, cladribine".	
RxA.653.Extavia	Dosing Information: Updated to include "Reconstitute lyophilized powder with supplied diluent; the removable diluent cap contains natural rubber latex". Initial Approval Criteria, I.A.2: Updated to include "(Avonex®, Betaseron®, Copaxone®, Vumerity®, Bafiertam®, Kesimpta®)". Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B, Drug Name: Updated to remove "natalizumab, ocrelizumab, alemtuzumab , interferon beta-1a , interferon beta-1b, peginterferon beta-1a, monomethyl fumarate, diroximel fumarate, teriflunomide, fingolimod, Siponimod, ozanimod, cladribine". Appendix D: Updated to include Warning and Precautions.	12/01/21
RxA.654.Vumerity	Background: Updated to include indication "Diroximel fumarate (Vumerity®) is indicated for the treatment…". Dosing Information, Maximum Dose: Updated from 462 mg twice a day to 924 mg/day. Dosing Information: Updated to include recommendation for severe renal impairment. Dosage Forms: Updated to remove "For oral administration...". Initial Approval Criteria, I.A.2: Updated to remove "Trial and failure of at least 2 preferred disease modifying therapies, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;". Initial Approval Criteria, I.A.6: Updated to split initial and maintenance dose. Initial Approval Criteria and Continued Therapy Approval Criteria, Approval Duration: Updated to remove HIM. Appendix B, Dosing Regimen and Maximum Dose: Updated to include specific info for all prior listed drugs and to remove unavailable generic drugs natalizumab, ocrelizumab, alemtuzumab, interferon beta-1a, interferon beta-1b, peginterferon beta-1a, monomethyl fumarate, teriflunomide, fingolimod and siponimod.	12/01/21
RxA.658.Kesimpta	No Update	12/01/21
RxA.661.Bafiertam	No Update	12/01/21

RxA.686.Ponvory	Initial Approval Criteria, I.A.4: Updated to include “Trial and failure of at least 2 preferred disease modifying therapies…”.	12/01/21

New Step Therapy

- Afrezza 8 unit (90)/ 12 unit (90) inhalation cartridge with inhaler
- Viibryd 10 mg (7)-20 mg (23) tablets in a dose pack

Updated Step Therapy

Drug Name; Strength(s); & Dosage Form(s)	Step Edit Details	Effective Date
None	None	None