Commissioner for the Department for Medicaid Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner of the Department for Medicaid Services (DMS) based on the Drug Review and Options for Consideration document prepared for the Pharmacy and Therapeutics (P&T) Advisory Committee's review on **September 21, 2017**, and the resulting official Committee recommendations.

New Products to Market

Arymo™ ER – Non-prefer in the PDL class: *Narcotics: Long-Acting*
Length of Authorization: 6 months

Arymo™ ER (morphine sulfate extended-release), an opioid agonist with abuse-deterrent properties, is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in adults for which alternative treatments are inadequate. It is available as 15 mg, 30 mg, and 60 mg tablets for oral administration every 8 or 12 hours.

Criteria for Approval:

- Prescriber is a Pain Management Specialist or prescriber has proof of consultation with a Pain Management specialist; AND
- Diagnosis of severe pain requiring daily, around-the-clock, long-term pain management, defined as:
  - Pain lasting >6 consecutive months; AND
  - Trial and failure of one non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without adequate relief of pain; AND
  - Trial and failure of one short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain; AND
- Trial and failure of two preferred long-acting opioids; AND
- Patient does NOT have a history of drug or alcohol abuse/dependence or addiction (drug and alcohol toxicology screen results dated within the past month must be submitted with the PA request); AND
- If the patient is female between the ages of 18 and 45 years of age, prescriber must attest to the fact that patient has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); AND
- Patient does NOT have respiratory depression, acute or severe bronchial asthma, or hypercarbia; AND
- Patient does NOT have paralytic ileus.

Age Limit = ≥ 18 years
Quantity Limit = 3 tablets per day

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MorphaBond™ – Non-prefer in the PDL class: *Narcotics: Long-Acting*
Length of Authorization: 6 months

MorphaBond™ (morphine sulfate extended-release), an opioid agonist with abuse-deterrent properties, is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in adults for which alternative treatments are inadequate. It is available as 15 mg, 30 mg, 60 mg, and 100 mg tablets for oral administration.

Criteria for Approval:

- Prescriber is a Pain Management Specialist or prescriber has proof of consultation with a Pain Management specialist; AND
- Diagnosis of severe pain requiring daily, around-the-clock, long-term pain management, defined as:
  - Pain lasting >6 consecutive months; AND
  - Trial and failure of one non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without adequate relief of pain; AND
  - Trial and failure of one short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain; AND
- Trial and failure of two preferred long-acting opioids; AND
- Patient does NOT have a history of drug or alcohol abuse/dependence or addiction (drug and alcohol toxicology screen results dated within the past month must be submitted with the PA request); AND
- If the patient is female between the ages of 18 and 45 years of age, prescriber must attest to the fact that patient has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); AND
- Patient does NOT have respiratory depression, acute or severe bronchial asthma, or hypercarbia; AND
- Patient does NOT have paralytic ileus.

Age Limit = ≥ 18 years
Quantity Limit = 2 tablets per day

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Drug Class	Preferred Agents	Non-Preferred Agents
Narcotics: Long-Acting	fentanyl transdermal 12, 25, 50, 75, 100 mcg CC, QL morphine sulfate SA (Generic for MS Contin®) QL	*Arymo™ ER CC, QL* *Belbuca™ QL* *buprenorphine patch CC, QL* *Butrans™ CC, QL* *ConZip™ QL* *Duragesic® CC, QL* *Embeda™ QL* *Exalgo™ QL* *fentanyl transdermal 37.5, 62.5, 87.5 mcg CC, QL* *hydromorphone ER QL* *Hysingla™ ER QL* *Ionsys® CC, QL* *Kadian® QL* *MorphaBond™ CC, QL* *morphine sulfate SA (Generic Kadian®, Avinza™) QL* *MS Contin® QL* *Nucynta® ER CC, QL* *oxycodone ER/SR QL* *OxyContin® QL* *oxymorphone ER QL* *tramadol ER QL* *Ultram® ER QL* *Xtampza™ ER QL* *Zohydro ER™ CC, QL*

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Xadago® – Non-prefer in the PDL class: *Parkinson's Disease*

Length of Authorization: 1 year

Xadago® (safinamide) is a monoamine oxidase type B (MAO-B) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes. Xadago® has not been shown to be effective as monotherapy for the treatment of Parkinson's disease. It is available as 50 mg and 100 mg tablets for oral administration.

Criteria for Approval:

- Diagnosis of Parkinson's disease (PD); AND
- Receiving PD therapy with carbidopa/levodopa; AND
- Experiencing "off" episodes with carbidopa/levodopa; AND
- Does not have severe hepatic impairment (Child-Pugh Score > 9); AND
- Not taking ANY the following medications:
  - Dextromethorphan; OR
  - MAOIs (e.g., or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid); OR
  - Other serotonergic drugs (e.g., SNRIs, SSRIs, TCAs, St. John's wort, cyclobenzaprine); OR
  - Opioids (e.g., meperidine, methadone, propoxyphene, tramadol); OR
  - Sympathomimetic medications (e.g., methylphenidate, amphetamine).

Age Limit = ≥ 18 years

Quantity Limit = 1 tablet per day

Drug Class	Preferred Agents	Non-Preferred Agents
Parkinson's Disease	amantadine syrup, capsules	*amantadine tablet*
	benztropine	*Azilect®*
	carbidopa	*Duopa™*
	Comtan®	*entacapone*
	levodopa/carbidopa	*levodopa/carbidopa/entacapone*
	levodopa/carbidopa CR	*Lodosyn®*
	levodopa/carbidopa ODT	*rasagiline*
	selegiline tablets	*Rytary™*
	trihexyphenidyl	*selegiline capsules*
		Sinemet®
		Sinemet® CR
		Stalevo®
		Tasmar®
		tolcapone
		Xadago® QL
		Zelapar™

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Tymlos™ – Non-prefer in PDL class: *Bone Resorption Suppression and Related Agents*
Length of Authorization: 1 year

Tymlos™ (abaloparatide), a parathyroid hormone (PTH) receptor-1 agonist, is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, abaloparatide reduces the risk of vertebral fractures and non-vertebral fractures. Cumulative use of Tymlos™ and other parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended due to a dose-dependent increase in osteosarcoma observed in rodents. It is available in a pre-filled pen device containing 3120 mcg/1.56 mL (thirty 80 mcg doses) solution for subcutaneous injection.

Criteria for Approval:

- Diagnosis of post-menopausal osteoporosis; AND
- Documented hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ –2.5 (standard deviations); AND
- Patient is at a high risk for fractures; AND
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone, bone metastases or skeletal malignancies, etc.); AND
- Patient has not received therapy with parathyroid hormone analogs (e.g., teriparatide) in excess of 24 months in total; AND
- Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial (to allow for repeat DXA) on previous therapy with oral bisphosphonates (e.g., alendronate, risedronate, ibandronate); AND
- Trial and failure of at least 1 preferred medication.

Renewal Criteria:

- Disease response (absence of fractures); AND
- Total length of therapy has not exceeded 24 months.

Age Limit = ≥ 18 years
Quantity Limit = 1 pen per 30 days

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Drug Class	Preferred Agents	Non-Preferred Agents
Bone Resorption Suppression and Related Agents	alendronate tablets QL raloxifene	*Actonel® QL* *alendronate solution QL* *Atelvia™ QL* *Binosto® QL* *Boniva® QL* *calcitonin-salmon* *etidronate* *Evista®* *Forteo™ QL* *Fosamax® QL* *Fosamax Plus D™ QL* *ibandronate QL* *Miacalcin®* *Prolia™* *Reclast® QL* *risedronate QL* *Tymlos™ QL* *zoledronic acid QL*

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Kevzara® – Non-prefer in the PDL class: *Immunomodulators*

Length of Authorization: 1 year

Kevzara® (sarilumab) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adults with moderately to severely active rheumatoid arthritis who had an inadequate response or intolerance to 1 or more disease-modifying antirheumatic drug(s). It is available in pre-filled syringes containing 150 mg/1.14 mL or 200 mg/1.14 mL solution for subcutaneous injection; each carton contains 2 doses.

Criteria for Approval:

- Diagnosis of moderately to severely active rheumatoid arthritis (RA); AND
- Trial and failure (at least 3 months) of at least 1 oral disease-modifying antirheumatic drug (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, leflunomide, etc.; AND
- Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®).
- Negative tuberculosis (TB) screening prior to initiating treatment; AND
- Kevzara® will not be used with a TNFα inhibitor (e.g., Enbrel®, Humira®) or other biologic DMARD (e.g., Actemra®, Orencia®)

Renewal Criteria:

- Meet initial approval criteria; AND
- Ongoing monitoring for TB; AND
- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts.

Age Limit = ≥ 18 years

Quantity Limit = 1 carton per 28 days

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Siliq™ – Non-prefer in the PDL class: *Immunomodulators*

Length of Authorization: 6 months

Siliq™ (brodalumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. Siliq™ has a risk evaluation and mitigation strategies program in place because of suicidality observed in clinical trials. It is available in a pre-filled syringe containing 210 mg/1.5 mL solution for subcutaneous injection; each carton contains two doses.

Criteria for Approval:

- Diagnosis of moderate to severe plaque psoriasis; AND
- Symptoms persistent for ≥ 6 months with at least 1 of the following:
  - Involvement of at least 10% of body surface area (BSA); OR
  - Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR
  - Incapacitation due to plaque location (i.e., head and neck, palms, soles or genitalia); AND
- Negative tuberculosis (TB) screening prior to initiating treatment; AND
- Patient does not have a history of Crohn's disease; AND
- Trial and failure of **two** of the following therapies:
  - Methotrexate
  - Cyclosporine
  - Oral retinoid (e.g., Soriatane®, acitretin)
  - Topical corticosteroids
  - Phototherapy/UV light
  - Coal tar preparations; AND
- Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®).

Renewal Criteria:

- Patient continues to meet criteria identified above; AND
- Ongoing monitoring for TB; AND
- Disease response as indicated by improvement in signs and symptoms compared to baseline, such as redness, thickness, scaliness, and/or the amount of surface area involvement.

Age Limit = ≥ 18 years

Quantity Limits:

Loading Dose = 2 cartons during the first 28 days

Maintenance Dose = 1 carton every 28 days

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Drug Class	Preferred Agents	Non-Preferred Agents
Immunomodulators	Enbrel® CC QL Humira® CC, QL	*Actemra® CC, QL* *Cimzia® CC, QL* *Cosentyx® CC, QL* *Entyvio™ CC, QL* *Kevzara® CC, QL* *Kineret® CC, QL* *Orencia® CC, QL* *Otezla® CC, QL* *Remicade® CC* *Siliq™ CC, QL* *Simponi™ CC, QL* *Simponi™ ARIA CC, QL* *Stelara™ CC, QL* *Taltz® CC* *Xeljanz™ CC, QL*

Trulance® – Non-prefer in the PDL class: *GI Motility Agents*

Length of Authorization: 1 year

Trulance® (plecanatide) is a guanylate cyclase-C agonist indicated for the treatment of chronic idiopathic constipation in adult patients. It is available as a 3 mg tablet for oral administration.

Criteria for Approval:

- Diagnosis of chronic idiopathic constipation; AND
- Trial and failure of, or contraindication to, at least 2 preferred agents, one of which must be Linzess® (linaclotide).

Age Limit = ≥ 18 years

Quantity Limit = 1 tablet per day

Drug Class	Preferred Agents	Non-Preferred Agents
GI Motility Agents	Amitiza® CC Linzess® CC Movantik® CC	*alosetron CC* *Lotronex® CC* *Relistor® oral CC, QL* *Trulance® CC, QL* *Viberzi® QL*

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AirDuo™ RespiClick® – Non-prefer in the PDL class: *Beta Agonists: Combination Products*

Length of Authorization: 1 year

AirDuo™ RespiClick® (fluticasone propionate and salmeterol) is a fixed dose combination product containing a corticosteroid and a long-acting beta agonist indicated for treatment of asthma in patients aged 12 years and older. It is available in 55 mcg/14 mcg, 113 mcg/14 mcg, and 232 mcg/14 mcg strengths as an inhalation powder in the RespiClick® device, which contains 60 actuations.

Criteria for Approval:

- Diagnosis of asthma; AND
- Trial and failure of at least 2 preferred agents, one of which must be Advair® Diskus.

Age Limit = ≥ 12 years

Quantity Limit = 1 inhaler per 30 days

Drug Class	Preferred Agents	Non-Preferred Agents
Beta Agonists: Combination Products	Advair® Diskus QL Dulera® QL Symbicort® QL	*Advair® HFA QL* *AirDuo™ RespiClick® QL* *Breo® Ellipta® QL*

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Emflaza™ – Non-prefer in the PDL class: *Oral Steroids*

Length of Authorization: 1 year

Emflaza™ (deflazacort) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy in patients 5 years of age and older. It is available as oral tablets in 6 mg, 18 mg, 30 mg, and 36 mg strengths as well as an oral suspension containing 22.75 mg/1 mL.

Criteria for Approval:

- Diagnosis of Duchenne muscular dystrophy (DMD); AND
- Patient is currently receiving, or planning to receive, physical therapy; AND
- Patient has experienced 1 of the following adverse reactions directly attributable to previous therapy with prednisone:
  - Significant behavioral changes negatively impacting function at school, home, day care, etc.; OR
  - Significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex)

Renewal Criteria:

- Patient continues to receive physical therapy; AND
- Patient has received benefit from therapy, which may include 1 or more of the following supported by documentation (e.g., progress notes):
  - Stability, improvement or slowing of decline in motor function;
  - Stability, improvement or slowing of decline in respiratory function;
  - Stability, improvement or slowing of decline in sequelae related to diminished strength of stabilizing musculature (e.g., scoliosis, etc.);
  - Stability, improvement or slowing of decline in quality of life.

Administration: Dose based on weight; 0.9 mg/kg once daily.

Age Limit = ≥ 5 years

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Steroids	budesonide EC dexamethasone solution, tablets hydrocortisone methylprednisolone dose pack, tablets prednisolone solution prednisolone sodium phosphate prednisone dose pack, tablets, solution	*Celestone®* *Cortef®* *cortisone* *dexamethasone elixir* *dexamethasone intensol* *DexPak®* *Emflaza™ CC* *Entocort EC®* *Medrol®* *methylprednisolone 8 mg, 16 mg tablets* *Millipred®* *Orapred ODT® AE* *prednisone intensol* *prednisolone sodium phosphate ODT* *Rayos®* *Veripred 20®*

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Dupixent® – Non-prefer in the PDL class: *Immunomodulators, Atopic Dermatitis*

Length of Authorization: 1 year

Dupixent® (dupilumab) is an interleukin-4 receptor (IL-4) α-antagonist indicated for the treatment of adult patients with moderate to severe Atopic Dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent® can be used with or without topical corticosteroids; it is available as pre-filled syringes containing 300 mg/2 mL solution for subcutaneous injection; each carton contains 2 doses.

Criteria for Approval:

- Have a diagnosis of moderate to severe atopic dermatitis (AD) with ≥ 1 of the following:
  - Involvement of at least 10% of body surface area (BSA); OR
  - Scoring Atopic Dermatitis (SCORAD) score of 20 or more; OR
  - Investigator's Global Assessment (IGA) with a score ≥ 3; OR
  - Eczema Area and Severity Index (EASI) score of ≥ 16; OR
  - Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); AND
- Have a prior documented trial (3 month minimum) and failure (or contraindication) of at least 1 agent in each of the following categories:
  - Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone); AND
  - Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); AND
  - Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); AND
- Trial and failure of phototherapy (e.g., psoralens with UVA light [PUVA], UVB, etc) – provided patient has reasonable access to this treatment; AND
- Is not pregnant.

Renewal Criteria:

- Continue to meet above criteria; AND
- Documented response compared to baseline as measured by measures used to qualify moderate to severe AD at baseline (e.g., pruritus, BSA involvement, EASI, IGA, SCORAD).

Age Limit = ≥ 18 years

Quantity Limits:

Loading Dose = 1 carton per 14 days

Maintenance Dose = 1 carton per 28 days

Drug Class	Preferred Agents	Non-Preferred Agents
Immunomodulators, Atopic Dermatitis	Elidel®	*Dupixent® CC, QL* *Eucrisa™* *Protopic®* *tacrolimus*

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Kisqali® – Prefer with Clinical Criteria in the PDL class: *Oral Oncology Agents, Breast Cancer*

Length of Authorization: 6 months

Kisqali® (ribociclib) is an inhibitor of cyclin-dependent kinase (CDK) 4 and 6 indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer. Kisqali® is available as 200 mg tablets for oral administration.

Criteria for Approval:

- Patient has a diagnosis of advanced or metastatic breast cancer that is:
  - Hormone receptor (HR)-positive; AND
  - Human epidermal growth factor receptor 2 (HER2)-negative; AND
- Is being used as first-line therapy in combination with an aromatase inhibitor; AND
- Female patients must be postmenopausal.

Renewal Criteria:

- Patient continues to meet initial review criteria; AND
- Lack of disease progression or decrease in tumor size.

Age Limit = ≥ 18 years

Quantity Limit = 63 tablets per 28 days

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Oncology Agents, Breast Cancer	Ibrance® QL Tykerb® QL anastrozole exemestane Kisqali® CC, QL letrozole tamoxifen citrate Xeloda®	*Arimidex®* *Aromasin®* *capacetabine* *cyclophosphamide* *Fareston®* *Faslodex®* *Femara®*

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Rydapt® – Prefer with Clinical Criteria in the PDL class: *Oral Oncology Agents, Hematologic Cancer*

Length of Authorization: 1 year

Rydapt® (midostaurin) is an oral tyrosine kinase inhibitor indicated for the treatment of adult patients with newly diagnosed, FLT3 mutation-positive acute myeloid leukemia, as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Rydapt® is also approved as single-agent therapy for the treatment of aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, and mast cell leukemia. Rydapt® is available as 25 mg capsules for oral administration.

Acute Myeloid Leukemia (AML)

Criteria for Approval:

- Patient must be newly diagnosed with AML (excluding acute promyelocytic leukemia); AND
- Patient's is FLT3 mutation-positive as detected by an FDA-approved test (e.g., Leukostrat CDx FLT3 Mutation Assay); AND
- Must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy (may not be used as a single-agent induction therapy).

Systemic Mastocytosis (SM)

Criteria for Approval:

- Patient has a diagnosis of 1 of the following:
  - Aggressive systemic mastocytosis (ASM); OR
  - Systemic mastocytosis with associated hematologic neoplasm (SM-AHN); OR
  - Mast cell leukemia (MCL).

Renewal Criteria:

- Tumor response, stabilization of disease or decrease in clinical findings.

Age Limit = ≥ 18 years

Quantity Limits:

Acute Myeloid Leukemia = 56 capsules per 21 days

Systemic Mastocytosis = 8 capsules per day

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Oncology Agents, Hematologic Cancer	Alkeran® cladribine Gleevec® QL hydroxyurea Imbruvica™ CC, QL Jakafi™ CC, QL mercaptopurine Purixan® Rydapt® CC, QL Sprycel® QL Zolinza® QL Zydelig® CC, QL	*Bosulif® QL* *Farydak® QL* *Hydrea®* *Iclusig™ QL* *imatinib QL* *Leustatin®* *melphalan* *Ninlaro™* *Purinethol®* *Tasigna® QL* *Venclexta® QL*

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Alunbrig™ – Non-prefer in the PDL class: *Oral Oncology Agents, Lung Cancer*
Length of Authorization: 1 year

Alunbrig™ (brigatinib) is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have experienced disease progression on, or are otherwise intolerant to, treatment with crizotinib (Xalkori®). Alunbrig™ is available as 30mg tablets for oral administration.

Criteria for Approval:

- Diagnosis of non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test; AND
- History of trial and failure of, or intolerance to, crizotinib (Xalkori®).

Age Limit = ≥ 18 years
Quantity Limit = 6 tablets per day

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Oncology Agents, Lung Cancer	Iressa® QL Tarceva® QL Xalkori® CC, QL	*Alecensa® QL* *Alunbrig™ QL* *Gilotrif™ QL* *Tagrisso™ QL* *Zykadia™ QL*

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Zejula® – Non-prefer in the PDL class: *Oral Oncology Agents, Other*

Length of Authorization: 1 year

Zejula® (niraparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, PARP-1 and PARP-2, and acts to increase the formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death. Zejula® is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. It is available as 100 mg capsules for oral administration.

Criteria for Approval:

- Diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; AND
- Agent is being used as monotherapy; AND
- Therapy to begin no later than 8 weeks after the most recent platinum-containing regimen; AND
- Must have had disease improvement or stabilization with platinum-based chemotherapy; AND
- No diagnosis or history of Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML).

Age Limit = ≥ 18 years

Quantity Limit = 3 capsules per day

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Oncology Agents, Other	Cometriq™ QL temozolomide	*capecitabine* *Caprelsa® QL* *Lonsurf®* *Lynparza™ QL* *Rubraca™ QL* *Stivarga® CC, QL* *Temodar®* *Zejula™ CC, QL*

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Class Review and Criteria Reviews

Yosprala™ Criteria Review

Current Criteria:

- Has the patient had a therapeutic trial and treatment failure of at least 1 preferred drug? Document the details; OR
- Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include:
  - Adverse reaction to preferred drugs; OR
  - Allergy to preferred drugs; OR
  - Contraindication to preferred drugs.

Recommended Changes:

Length of Authorization: 1 year

- Patient has ≥ 1 of the following:
  - History of ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli; OR
  - History of myocardial infarction (MI); OR
  - Unstable angina pectoris; OR
  - Chronic stable angina pectoris; OR
  - History of revascularization procedures (CABG or PCA); AND
- Patient requires aspirin therapy for ≥ 6 months; AND
- Age 55 or older; OR
- History of gastric or duodenal ulcer within the past 5 years; AND
- Demonstrated non-adherence to individual components (aspirin and omeprazole) and/or aspirin and 1 preferred proton pump inhibitor (PPI).

Age Limit = ≥ 18 years

Quantity Limit = 1 tablet per day

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Antianxiety Agents Criteria Review

Current PDL Criteria:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval;
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval;
- History of unacceptable/toxic side effects to medications not requiring prior approval

The requested non-preferred medication may be approved if both of the following are true:

- If there has been a therapeutic failure to no less than 2 preferred medications; AND
- The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated

Current Maximum Duration (MD) Criteria:

All benzodiazepines are available without a prior authorization for the first 60 days per 365-day period. For therapy beyond 60 days, prior authorization is required and may be approved as follows:

Approve for 1 month for the following diagnosis:

- Acute alcohol withdrawal

Approve for 6 months for the following diagnoses / situations:

- Agoraphobia
- Anxiety
- Anxiety disorder
- Chemotherapy-induced nausea & vomiting
- Depression
- Panic attacks or panic disorder
- Social phobia
- Status epilepticus

Approve for 1 year for the following diagnosis:

- Seizures

For all other diagnoses:

Requests will be reviewed by a Clinical Pharmacist on a case-by-case basis for approval consideration. These requests must be accompanied by medical literature published in a peer reviewed journal.

No recommended changes.

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Sedative Hypnotic Agents Criteria Review

Current PDL Criteria:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval;
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and
- History of unacceptable/toxic side effects to medications not requiring prior approval

The requested non-preferred medication may be approved if both of the following are true:

- If there has been a therapeutic failure to no less than 2 preferred medications; AND
- The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated

Current Quantity Limits:

- All agents are subject to a quantity limit of 1 per day; EXCEPT
  - Triazolam 0.25mg is allowed 2 per day.

Recommended changes:

Maximum Duration (MD) Criteria

- All sedative hypnotics shall have a maximum duration edit that is in line with the prescribing information (PI).

DMS Commissioner Decision

- The details of the package insert for each product in this class will be presented at the next P&T Committee meeting prior to a final decision.

Angiotensin Modulators

Class Selection & Guidelines

Angiotensin Converting Enzyme Inhibitors (ACEI)

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Angiotensin Converting Enzyme Inhibitors (ACEI)* class require PA until reviewed by the P&T Advisory Committee.

ACEI + Diuretic Combinations

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.

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- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *ACEI + Diuretic Combinations* class require PA until reviewed by the P&T Advisory Committee.

Angiotensin Receptor Blockers (ARB)

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Angiotensin Receptor Blockers (ARB)* class require PA until reviewed by the P&T Advisory Committee.

ARB + Diuretic Combinations

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *ARB + Diuretic Combinations* class require PA until reviewed by the P&T Advisory Committee.

Direct Renin Inhibitors

- DMS to select preferred agent(s) based on economic evaluation.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Direct Renin Inhibitors* class require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
ACE Inhibitors	benazepril lisinopril quinapril ramipril	*Altace®* *captopril* *enalapril* *Epaned™* *fosinopril* *moexipril* *perindopril* *Prinivil®* *Qbrelis™* *trandolapril* *Vasotec®* *Zestril®*
ACEI + Diuretic Combinations	benazepril/HCTZ lisinopril/HCTZ	*captopril/HCTZ* *enalapril/HCTZ* *fosinopril HCT* *moexipril/HCTZ* *quinapril/HCTZ* *Zestoretic®*

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Drug Class	Preferred Agents	Non-Preferred Agents
Angiotensin Receptor Blockers	losartan valsartan	*Atacand®* *Avapro®* *Benicar®* *candesartan* *Cozaar®* *Diovan®* *Edarbi™* *Entresto™ CC* *eprosartan* *irbesartan* *Micardis®* *telmisartan*
ARB + Diuretic Combinations	losartan/HCTZ valsartan/HCTZ	*Atacand HCT®* *Avalide®* *Benicar HCT®* *candesartan/HCTZ* *Diovan HCT®* *Edarbyclor™* *Hyzaar®* *irbesartan/HCTZ* *Micardis HCT®* *telmisartan/HCTZ*
Direct Renin Inhibitors	N/A	*Tekturna® ST* *Tekturna HCT® ST*

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Topical Antifungal Agents

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Topical Antifungal Agents* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Topical Antifungal Agents	clotrimazole cream, solution clotrimazole/betamethasone ketoconazole cream, shampoo nystatin cream, ointment, powder nystatin/triamcinolone ointment	*Ciclodan® cream, kit, solution* *ciclopirox* econazole *Ertaczo®* *Exelderm®* *Extina®* *Jublia® CC* *Kerydin™ CC* *ketoconazole foam* *Ketodan™* *Loprox®* *Lotrimin®* *Lotrisone®* *Luzu®* *Mentax®* *naftifine* *Naftin®* *Nizoral Shampoo®* *Nyamyc®* *nystatin/triamcinolone cream* *Nystop®* *Oxistat®* *oxiconazole* *Penlac®* *Therazole Pak™ QL* *Vusion® CC* *Xolegel®*

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Beta Blockers

Class Selection & Guidelines

Alpha/Beta Blockers

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Alpha/Beta Blockers* class, require PA until reviewed by the P&T Committee.

Beta Blockers

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Beta Blockers* class, require PA until reviewed by the P&T Committee.

Beta Blockers + Diuretic Combinations

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Beta Blockers + Diuretic Combinations* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Alpha/Beta Blockers	carvedilol labetalol	*Coreg®* *Coreg CR®*
Beta Blockers	atenolol metoprolol tartrate metoprolol succinate ER propranolol propranolol ER	*acebutolol* *betaxolol* *bisoprolol* *Bystolic™* *Corgard®* *Hemangeol™* *Inderal® LA* *Inderal® XL* *Innopran XL®* *Levatol®* *Lopressor®* *nadolol* *pindolol* *Tenormin®* *timolol* *Toprol XL®*

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Drug Class	Preferred Agents	Non-Preferred Agents
Beta Blockers + Diuretic Combinations	atenolol/chlorthalidone bisoprolol/HCTZ	*Corzide®* *Dutoprol™* *Lopressor® HCT* *metoprolol tartrate/HCTZ* *nadolol/bendroflumethiazide* *propranolol/HCTZ* *Tenoretic®* *Ziac®*

Leukotriene Modifiers

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Leukotriene Modifiers* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Leukotriene Modifiers	montelukast chewable, tablet QL montelukast granules AE, QL	*Accolate® QL* *Singulair® QL* *zafirlukast QL* *Zyflo® QL* *Zyflo CR® QL*

Montelukast Granules Age Edit Addition:

- Montelukast granules for patients under 6 years of age: no prior authorization required.
- Montelukast granules for patients 6 years of age and older: approval requires a clinically valid reason why the tablets OR chewable cannot be used.

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Lipotropics: Statins

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Lipotropics: Statins* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Lipotropics: Statins	atorvastatin QL lovastatin QL pravastatin QL rosuvastatin QL simvastatin QL	*Altoprev®* QL *amlodipine/atorvastatin* QL *Caduet®* QL *Crestor®* QL *ezetimibe/simvastatin* QL *fluvastatin* QL *fluvastatin ER* QL *Lescol XL®* QL *Lipitor®* QL *Livalo®* QL *Pravachol®* QL *Vytorin™* QL *Zocor®* QL

Topical Rosacea Agents

New Product Addition to the Class: Rhofade™

Recommend non-prefer in this class.

Length of authorization: 1 year

- Rhofade™ (oxymetazoline hydrochloride 1% cream), an alpha 1A adrenoceptor agonist, is approved for the topical treatment of persistent facial erythema associated with rosacea in adults. It is available in 30 gram and 60 gram tubes and pumps for topical administration.

Criteria for Approval:

- Diagnosis of rosacea or facial erythema; AND
- Trial and failure of metronidazole; AND
- Trial and failure of at least one of the following: tetracycline, minocycline, doxycycline, erythromycin, clindamycin, or benzoyl peroxide.

Age Limit = ≥ 18 years

Quantity Limit = 60 grams per 30 days

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.

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- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Topical Rosacea Agents* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Topical Rosacea Agents	MetroCream® MetroGel® MetroLotion®	*Azelex®* *Finacea®* *metronidazole cream, gel* *metronidazole lotion* *Mirvaso®* *Noritate®* *RhoFade™* *Rosadan® Kit* *Soolantra®*

Classes Reviewed by Consent Agenda

No change in PDL status:

- Alzheimer's Agents
- Androgenic Agents
- Angiotensin Modulator Combinations
- Anticonvulsants
- Antidepressants, SSRIs
- Antihistamines, Minimally Sedating
- Antihyperuricemics
- Antiparasitics, Topical
- Antipsoriatics, Oral
- Antivirals, Topical
- Bladder Relaxant Preparations
- Erythropoiesis Stimulating Proteins
- Nasal Preparations – Antibiotics
- Otic Antibiotics
- Otics, Anti-Inflammatories
- PAH Agents – Oral and Inhaled
- Phosphate Binders
- Ulcerative Colitis Agents
- Vasodilators, Coronary

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Brand/Generic Switch:

- Antidepressants, Other

Drug Class	Preferred Agents	Non-Preferred Agents
Antidepressants: Other	bupropion bupropion XL bupropion SR trazodone	*Aplenzin™* *Trintellix™* *Forfivo XL™* *nefazodone* *Viibryd™* *Wellbutrin®* *Wellbutrin® SR* *Wellbutrin® XL*
Antidepressants: SNRIs	desvenlafaxine succinate ER (generic Pristiq®) Savella™ CC venlafaxine venlafaxine ER capsules	*Cymbalta®* *desvenlafaxine ER base* *desvenlafaxine fumarate ER* *duloxetine (Generic Irenka™)* *duloxetine DR (Generic Cymbalta®)* CC *Effexor®* *Effexor XR®* *Fetzima™* *Irenka™* *Khedezla®* *Pristiq®* *venlafaxine ER tablets*

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