### PHARMACY PRIOR AUTHORIZATION CRITERIA
**MOLINA HEALTHCARE OF UTAH MEDICAID/CHIP/MARKETPLACE**

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<th>BRAND NAME</th>
<th>GENERIC NAME</th>
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| ACTONEL | risedronate | 1. Treatment of Osteoporosis. Treatment and prevention of glucocorticoid-induced Osteoporosis.* Prevention of Osteoporosis in postmenopausal women with one or more additional risk factors besides menopause. Treatment of Paget's disease of bone, AND  
   *Documentation of bone mineral density (BMD) is required prior to initiating therapy for prevention of glucocorticoid-induced osteoporosis.  
2. Member has documented ineffectiveness, intolerance, or contraindication to alendronate or ibandronate. Note: If a claim cannot be verified in member's prescription history a copy of the Prescriber's chart note documenting the intolerance must be submitted for review.  

Quantity limited to:  
Actonel 35 mg: 4 tablets per month  
Actonel 75 mg: 2 tablets per month  
Actonel 150 mg: 1 tablet per month |
| TESTOSTERONE REPLACEMENTS | testosterone topical solution | 1. For male members18 years or older with a documented diagnosis of primary hypogonadism (congenital or acquired) or secondary hypogonadism (congenital or acquired), and  
2. Clinical documentation (laboratory value) of two (2) early morning (prior to 10am) testosterone lab values that confirm low testosterone (<300ng/dL) within the past 18 months, and  
3. Member does not have prostate carcinoma or breast carcinoma  

Quantity limited to:  
Axiron®: 2 x 90ml pumps per 30 days  
Fortesta®: 2 x 60g canisters per 30 days |
| ALBENZA | albendazole | Diagnosis only: cystic hydatid disease, or neurocysticercosis |
| ALDARA | imiquimod | Diagnosis of superficial basal cell carcinoma, external genital, or perianal warts, actinic keratosis, or molluscum contagiosum |
| ANTINEOPLASTIC AGENTS | imatinib gefitinib dasatinib erlotinib bexarotene lapatinib ditosylate thalidomide temsirolimus vorinostat | Must meet FDA-approved indications and prescriber is an Oncologist  
The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the member's medical records.  

Authorization and Limitations:  
- If FDA approved indication and prescriber specialty are met, initial authorizations is 3 months.  
- Prescriber must provide documentation of disease progression for consideration of continuation of treatment. If disease progression is not submitted, therapy may not be continued.  
- Quantity is limited to a maximum of a 30-day supply per fill. |
| ARICEPT | donepezil | Treatment of mild, moderate, or severe Alzheimer's disease. For 23mg oral tabs: Members have been on a dosage of donepezil 10 mg once daily for at least 3 months  

Quantity is limited to 1 tablet per day |
| BIOTECHNOLOGY AGENTS | Including: Interferons, ribavirin, Growth Hormone (Tev-Tropin) | Prior authorization of these agents may require completion of specific forms which will be automatically faxed to the prescriber under the standard prior authorization procedure. Distribution may be limited to specialty pharmacy at the discretion of Molina.

*Molina Staff: Refer to MCGs

| BILTRICIDE | praziquantel | Treatment of infections caused by the following: all species of Schistosoma (eg, *Schistosoma mekongi*, *S. japonicum*, *S. mansoni*, *S. hematobium*) and the liver flukes

| BYETTA | exenatide | Diagnosis of type 2 diabetes mellitus and meets one of the following criteria:

1. Hemoglobin A1C is <9 but still not at goal while on metformin in combination with a TZD and/or DPP-IV,
2. All three classes of medications (metformin, sulfonylureas, and thiazolidinediones) are contraindicated for this patient (e.g., due to drug-drug or drug-disease interactions or because the patient was unable to tolerate treatment).

*Not approved for convenience or if non-compliance with other therapies.
*Not recommended as first-line therapy for patients who have inadequate glycometric control on diet and exercise.
*Requests for weight loss are not approvable

| CARAC | fluorouracil 0.5% cream | Topical treatment of multiple actinic or solar keratoses. Prescribed by dermatologist; members 18 years of age or older. Documented failure, intolerance or contraindication to fluorouracil (Efudex generic) cream.

| CELEBREX | celecoxib | Prescribed for an FDA-approved indication and documented trial and failure of three formulary NSAIDs

| COMBIPATCH | estradiol/norethindrone | 1. Treatment of moderate to severe vasomotor symptoms in menopause, vulvar/vaginal atrophy; treatment of hypoestrogenisms due to hypogonadism, castration, or primary ovarian failure, AND
2. Documented failure to formulary estrogen/progestin combination products (e.g., *Prempro* or *Premphase*), OR history of failure to *Provera* or Intolerance to oral progestin formulation due to GI malabsorption

Quantity limited to: 8 patches per month

| DAYTRANA* "CARVED OUT FOR MEDICAID" | methylphenidate patch | Treatment of ADHD in patients 6 yr and older who are unable to take oral formulations due to specific medical condition. “Unable to swallow” justification must have prior failure to formulations with sprinkle capability (i.e., Metadate CD, Adderall XR)

| DDAVP Nasal Spray | desmopressin acetate 0.01%, nasal spray | Diagnosis of central diabetes insipidus. Ineffective for the treatment of nephrogenic diabetes insipidus.

| DIPEPTIDYL-PEPTIDASE-IV (DPP-IV) INHIBITORS | sitagliptin | On minimum 1 gm BID metformin AND A1c ≤ 9 AND have filled metformin AND Actos OR sulfonylurea 3 of the last 4 months OR documented adverse drug reaction to Actos or sulfonylurea

| JANUVIA JANUMET JENTADUETO TRADJENTA | sitagliptin/sitagliptin/metformin, linagliptin, linagliptin/metformin | Diagnosis of severe chronic pain and documented failure of or experienced intolerance to oral formulary long-acting analgesic

| DURAGESIC PATCHES | fentanyl patches | Diagnosis of severe chronic pain and documented failure of or experienced intolerance to oral formulary long-acting analgesic
<table>
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<tr>
<th>Brand Name</th>
<th>Description</th>
<th>Criteria</th>
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</thead>
<tbody>
<tr>
<td>EFUDEX</td>
<td>fluorouracil cream (5% strength)</td>
<td>Treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesion sites.</td>
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<tr>
<td>EXELON PATCH</td>
<td>rivastigmine</td>
<td>Diagnosis of Alzheimer’s or vascular dementia or Dementia associated with Parkinson’s disease or dementia with Lewy bodies (DLB) and failure to rivastigmine capsules.</td>
</tr>
<tr>
<td>FOCALIN XR*</td>
<td>dexamethasone HCl</td>
<td>Treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age and older.</td>
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</table>
| FORTEO     | teriparatide (Recombinant)                                                    | For the treatment of postmenopausal women with osteoporosis who are at high risk of fracture or men with primary or hypogonadal osteoporosis who are at high risk for fracture and meet the following criteria (a, b and c):  
  a. Have a bone mineral density (BMD) that is 2.5 standard deviations or more below the mean (T-score at or below -2.5).  
  b. Member has tried and failed a bisphosphonate for a 24 month period except when:  
    - contraindication to a bisphosphonate (such as a stricture or achalasia, inability to sit upright for at least 30 minutes and increased risk of aspiration).  
    - documented intolerance to a bisphosphonate  
  OR  
    - documented intolerance to a bisphosphonate  
For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture. Member must meet ALL of the following criteria:  
  a. Member has osteoporosis associated with chronic systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone)  
  b. Member has “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.  
  c. Documentation of trial and failure to alendronate, ibandronate, or risedronate; or documented intolerance to alendronate, ibandronate, or risedronate  
  c. Coverage will NOT be provided in the following situations:  
    1. Concurrent treatment with a bisphosphonate  
    2. Hypercalcemia  
    3. Paget’s disease  
    4. Bone metastases or a history of skeletal malignancies  
    5. Metabolic bone disease other than osteoporosis  
    6. Pediatric members or young adults with open epiphyses  
    7. Prior radiation therapy involving the skeleton  
*Forteo may be authorized for a maximum of two years. |
<p>| GEODON*    | ziprasidone                                                                  | Treatment of schizophrenia or bipolar disorder                                                                                                                                                    |</p>
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| **INTUNIV**  
*CARVED OUT FOR MEDICAID*  
guanfacine Extended Release  
For the treatment of attention deficit hyperactivity disorder (ADHD) in members 6 to 17 years of age who have met the following conditions:  
a. Trial and failure or intolerance to immediate-release guanfacine [Guanfacine (generic)]  
b. Trial and failure or intolerance of at least TWO (2) formulary stimulants OR Documented condition that contraindicates the use of preferred stimulants (i.e. seizure disorders, significant anxiety, oppositional defiant disorder, Tourette’s syndrome or other motor tics) OR Documented personal history of substance abuse or misuse  
*The recommended dose for 6 to 17 years of age is 1-4 mg once daily. Do not authorize doses exceeding the recommended.*  |
| **ISOTRETINOIN**  
AMNESTEEM  
CLARAVIS  
SOTRET  
isotretinoin  
Treatment of severe (i.e., many nodules) recalcitrant nodular acne AND member experienced a failure with a trial of at least one oral antibiotic in conjunction with two topical anti-acne topical agents including tretinoin and an antibiotic AND requesting physician a dermatologist  |
| **LOVENOX**  
enoxaparin  
Prescribed for an FDA-approved indication AND documentation of ONE of the following:  
- Intolerance or contraindication to warfarin and heparin, or  
- Need for bridge to Coumadin, or  
- Knee or hip arthroplasty.  
*May fill ≤ 7 day supply at retail; continued use – Caremark Specialty Pharmacy*  |
| **LUVOX**  
*CARVED OUT FOR MEDICAID*  
fluvoxamine maleate  
Documentation of previous trial and therapy failure with the immediate release product of the same chemical entity, unless evidence is provided that use of the immediate release product would be medically contraindicated.  |
| **MARINOL**  
dronabinol  
Prescribed for control of chemotherapy-induced nausea and vomiting unresponsive to other antiemetics AND have adequate trial and therapeutic failure of at least 2 formulary anti-emetic medications including ondansetron  
Not covered for appetite stimulation in AIDS cachexia  |
| **MIACALCIN**  
(INJECTION)  
calcitonin-salmon injection  
Postmenopausal Osteoporosis  
1. Failure to a bisphosphonate or selective estrogen-receptor modulator (SERM); AND  
2. Failure to Micacidin Nasal Spray; AND  
3. History of vertebral compression fractures, or fractures of the hip or distal radius resulting from minimal trauma, or T score of -2.5 or less.  
*Paget's Disease*  
History of failure or intolerance to oral bisphosphonates.  
*Hypercalcemia*  
1) Corrected total serum calcium of 12 mg/dl; OR 2) Greater or corrected total serum calcium of 6 mEq/L or greater. Approve only 1 month.  |
| **MIACALCIN NASAL SPRAY**  
calcitonin (salmon) nasal soln 200 unit/act  
Treatment of postmenopausal osteoporosis in females greater than 5 years post-menopause with low bone mass.  |
| **NAMENDA** | memantine | Treatment of moderate to severe dementia of the Alzheimer type. |
| **ONFI** | clobazam | Treatment of seizures related to Lennox-Gastaut Syndrome. Prescribed by board-certified neurologist. Recurrent seizures despite trial of 2 or more medications FDA-approved agents for LGS [such as Lamictal (lamotrigine), Topamax (topiramate), Felbatol (felbamate), Banzel (rufinamide), Klonopin, (clonazepam)] |
| **OXYCONTIN** | oxycodone CR | Treatment of severe chronic pain with documented failure on other formulary long-acting analgesics; documented evaluation/recommendation by pain management specialist or oncology; Approved only for QD or BID dosing, no PRN use |
| **PROGESTERONE, Intramuscular** | progesterone Intramuscular oil, 50 MG/ML | Amenorrhea and abnormal uterine bleeding: For the treatment of amenorrhea and abnormal uterine bleeding caused by hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer. |
| **PROTOPIC** | tacrolimus | Treatment of short-term and intermittent long-term therapy of mild to moderate atopic dermatitis in patients > 2 years of age; failure of topical steroids. 30g quantity max. |
| **PROTON PUMP INHIBITORS (> 6 months use)** | lansoprazole omeprazole pantoprazole | Documentation of one of the following conditions: Pathological hypersecretory conditions including Zollinger-Ellison syndrome. Barrett's esophagus Multiple endocrine adenomas Systemic mastocytosis in adults Continued symptoms after an adequate trial off proton pump inhibitor therapy |
| **RAPAMUNE** | sirolimus | Prophylaxis of organ rejection in patients receiving allogeneic renal transplants. Patient is at least 13 years of age. |
| **RETIN-A MICRO GEL** | tretinoin microsphere | Documented medical necessity why generic tretinoin cannot be used |
| **REVLIMID** | lenalidomide | Refer to Medical Coverage Guidance MCG-064 |
| **RISPERDAL** *CARVED OUT FOR MEDICAID | risperidone tabs | Treatment of psychotic disorders. Prescribed by a psychiatrist. |
| **RISPERDAL CONSTA** *CARVED OUT FOR MEDICAID | risperidone microspheres | Members must be 18 years or older, have a diagnosis of Bipolar Disorder or Schizophrenia, AND be under treatment by or in consultation with a psychiatrist. In addition, documentation must be submitted to demonstrate one of the following: the member has already been started and stabilized on this medication, member has history of noncompliance, or member is unable to swallow oral dosage forms. NOTE: Member must not currently be on oral risperidone, or will discontinue oral risperidone within 60 days after Risperdal® Consta® is initiated. |
| **RISPERIDONE M-TAB** *CARVED OUT FOR MEDICAID | risperidone tablet dispersible | Members who are unable to swallow, OR unable to absorb medications through the GI tract. |
| **SEROQUEL**<sup>*</sup>  
*CARVED OUT FOR MEDICAID | quetiapine | Documented diagnosis of Schizophrenia or Bipolar I disorder AND prescribed by a Psychiatrist.  
Not approvable when prescribed as an adjunct to Major Depressive Disorder (MDD), or to treat insomnia |
| **SEROQUEL XR**<sup>*</sup>  
*CARVED OUT FOR MEDICAID | quetiapine Extended Release 24 Hr | 1. For members 18 years or older with a diagnosis of Bipolar Disorder, Major Depressive Disorder (MDD) or Schizophrenia AND  
2. Documentation that the member has had an inadequate response due to intolerance, side effects, or lack of efficacy to other antipsychotics (including immediate release quetiapine), or other psychotropic medications used to treat the diagnosis |
| **SKELID** | tiludronate disodium | Documented diagnosis of Paget’s disease AND member has tried and failed a generic alendronate or Boniva, or has a contraindication to the use of generic alendronate or Boniva (for which would not be a contraindication to the use of Skelid). Quantity limited to 2 tablets per day |
| **SMOKING CESSATION AGENTS** | nicotine, Nicotrol products, Chantix | For smoking cessation. Treatment course limited to 3 months. Member must be enrolled in smoking cessation program. Limit of one trial every 52 weeks |
| **SYNAREL** | nafarelin acetate, nasal solution | Diagnosis of central precocious puberty with the onset of secondary sexual characteristics earlier than 8 years of age in females and 9 years of age in males, OR diagnosis of endometriosis for member greater than 18 years of age |
| **STIMATE** | desmopressin acetate 1.5mg/mL, nasal spray | Diagnosis of hemophilia A with factor VIII coagulant activity levels more than 5% OR diagnosis of mild-to-moderate classic von Willebrand's disease (Type I)* with Factor VIII levels > 5% and evidence of an abnormal molecular form of Factor VII antigen  
*Stimate should not be used in the treatment with Type IIB von Willebrand's disease, |
| **STRIBILD** | cobicistat, elvitegravir, emtricitabine and tenofovir | Prescribed for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve (documentation that member has never been on any antiretroviral treatment required). Medical justification must be provided demonstrating why Atripla can not be used instead. Member is age 18 to 65. Prescriber specialty is infectious disease. |
| **STROMECTOL** | ivermectin | Documented diagnosis of strongyloidiasis of the intestinal tract, onchocerciasis, or resistant head and body lice. |
| **SUBOXONE** | buprenorphine HCl- naloxone HCl Dihydrate | Refer to Medical Coverage Guidance MCG-072 for Suboxone criteria. |
| **TAZORAC GEL** | tazarotene | Treatment of stable plaque psoriasis. Treatment of cystic acne, prescribed by dermatologist (0.1% only). |
| **TOFRANIL-PM**<sup>*</sup>  
*CARVED OUT FOR MEDICAID | Imipramine pamoate | Member has had an intolerance to, or treatment failure of imipramine tablets (Tofranil tablets). A claim in the member’s prescription history for imipramine (Tofranil) or documentation from Prescriber’s chart note indicating the intolerance must be submitted for review.  
*Per the Beers list, imipramine is highly anticholinergic, sedating, and can cause orthostatic hypotension. Avoid use in elderly patients [American Geriatrics Society 2012 Beers Criteria Update Expert Panel] |
| **TOPAMAX**<sup>*</sup> sprinkle cap, tabs  *CARVED OUT FOR MEDICAID | topiramate | Treatment of seizures, with therapy initiated by neurology; not approved for psychiatric use.  
For the prophylaxis of migraine headache in adults. The use of topiramate in the acute treatment of migraine headache has not been studied. |
|---|---|---|
| **VALCYTE** | valganciclovir (450mg tablets only) | Prescribed for one of the following indications:  
1. Prevention of CMV disease in kidney, heart, or kidney-pancreas transplant patients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R−]).  
| **VANCOCIN** | vancomycin oral | Treatment of pseudomembranous colitis due to Clostridium difficile and failure on a regimen of metronidazole. |
| **VIGAMOX** | moxifloxacin | Must meet FDA-approved indications and trial and failure of ciprofloxacin and ofloxacin ophthalmic solutions. |
| **XOLOX** | oxycodone w/ acetaminophen | Treatment of moderate to severe pain when generic Percocet is not an option. |
| **ZETIA** | ezetimibe | For Zetia as monotherapy: member has documented intolerance or contraindication to statin therapy, nicotinic acid, fibrates and bile acid sequestrants.  
For Zetia as combination therapy with statins: Trial and failure of simvastatin 40mg or the maximum dose tolerated of simvastatin or of a comparably dosed statin agent (or a documented adverse reaction, intolerance or contraindication to simvastatin or statin agent), or a combination agent containing simvastatin or statin agent for at least 3 months.  
Documentation of lipid panel within previous 60 days indicating member is not within target LDL goal range according to ATP-III guidelines must be submitted. |
| **ZOCOR 80mg** | simvastatin 80mg | Documentation that member has been on a product containing simvastatin 80 mg for 12 months or more without evidence of muscle toxicity or myopathy.* Coverage will not be authorized for titration to or a new start of an 80 mg daily equivalent of simvastatin.  
*The FDA recommends that simvastatin 80 mg should only be used in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy). |
<p>| <strong>ZOFRAN SOLUTION</strong> | ondansetron solution | Prescribed for an FDA-approved indication and documentation of inability to swallow oral dosage forms. |
| <strong>ZYPREXA</strong>&lt;sup&gt;*&lt;/sup&gt;  *CARVED OUT FOR MEDICAID | olanzapine | Treatment of Psychotic Disorders and Bipolar Mania; Prescribed by Psychiatrist. |</p>
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<tr>
<td>ZYPREXA RELPREVV INJECTION*</td>
<td>olanzapine pamoate (suspension/IM)</td>
<td>Member must be 18 years or older, have a diagnosis of Psychotic Disorders and Bipolar Mania; Prescribed by a psychiatrist AND documentation of one of the following: 1) member has already been started and stabilized on this medication, 2) member has a history of non-compliance, or 3) member is unable to swallow oral dosage forms.</td>
</tr>
<tr>
<td>ZYPREXA ZYDIS*</td>
<td>olanzapine tablet dispersible</td>
<td>For 18 years or older: Prescribed for the adjunctive treatment for Major Depressive Disorder For 13 years or older: Treatment of schizophrenia or bipolar disorder AND Documentation of swallowing difficulty submitted.</td>
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These guidelines for prior approval are for reference, only. They do not replace the professional judgment of the prescribing physician and do not necessarily apply to all patient-specific situations. All requests are looked at on a case by case basis.

Use of pharmaceutical samples in lieu of Formulary first-line agents does not guarantee authorization.

To request a copy of a prior authorization request form, or to request full-length criteria for a medication listed above (if applicable), call (888) 483-0760.

*Updated 01/2014*