# Pharmacy Prior Authorization

## Non-Formulary, Prior Authorization and Step-Therapy Guidelines

Scroll down to see PA Criteria by drug class, or Ctrl+F to search document by drug name

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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</thead>
</table>
| **Non-Formulary Medication Guideline** | Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:  
- An appropriate diagnosis/indication for the requested medication,  
- An appropriate dose of medication based on age and indication,  
- Documented trial of at least 2 formulary agents for an adequate duration have not been effective or tolerated, OR  
- All other formulary medications are contraindicated based on the patient’s diagnosis, other medical conditions or other medication therapy, OR  
- There are no other medications available on the formulary to treat the patient’s condition | **Initial Approval:**  
- Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring  
**Renewal:**  
- Minimum of 6 months  
- Maintenance medications may be approved indefinitely |
| **Non-Formulary Diabetic Supplies** | **Diabetic Test Strip and Glucometer Quantity Limits:**  
- All diabetic test strips are limited to 150 ct/30 days  
- Glucometers are limited to 1 glucometer/12 months  
**Criteria to Receive Non-Formulary Diabetic Supplies**  
- Member with hematocrit level that is chronically less than 30% or greater than 55%  
- Member with physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product  
- Member with an insulin pump that requires a specific test strip | 1 year |
### Criteria to Receive > 150 Test Strips Per Month
- Members newly diagnosed with diabetes or with gestational diabetes
- Children with diabetes (age ≤ 12)
- Members on insulin pump
- Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily

### Criteria to Receive >1 Glucometer Per Year
- Current glucometer is unsafe, inaccurate, or no longer appropriate based on patients medical condition
- Current glucometer no longer functions properly, has been damaged, or was lost or stolen.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Medications requiring Prior Authorization</td>
<td>Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.</td>
<td>As documented in the individual guideline</td>
</tr>
<tr>
<td>Medications requiring Step Therapy</td>
<td>Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for medications that do not process automatically at the pharmacy.</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Brand Name Medication Requests</td>
<td>Aetna Better Health of New Jersey requires use of generic agents that are considered therapeutically equivalent by the FDA. For authorization of a brand name medication, please submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf</a></td>
<td>Indefinitely</td>
</tr>
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</table>
## Specialist Prescriber Medication Requests

Some medications are covered when prescribed by a Specialist prescriber. If the medication is prescribed by the appropriate Specialist, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, authorization will be given upon receipt of a Specialist Consult or after trial and failure of 2 formulary medications.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Authorization Guidelines/Criteria</th>
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</table>
| Acamprosate<sup>1</sup> (Campral) | For patients that meet all of the following:  
- Diagnosis of alcohol use disorder  
- Abstinent from alcohol  
- Enrolled in and compliant with substance abuse treatment program or psychosocial support plan  
- No evidence of severe renal impairment (CrCl <30 ml/min)  
- Failure or contraindication/intolerance to naltrexone or disulfiram  

**Initial Approval:**  
- 3 months  

**Renewal:**  
- 3 months  

**Requires:**  
Compliance with substance abuse treatment program or psychosocial support plan |
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<tbody>
<tr>
<td>ADHD Medication Age Limits</td>
<td>PA is required for members who are &lt;6 years old and &gt;18 years old.</td>
<td>1 Year</td>
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**Criteria for < 6 years old:**
- Diagnosis of ADHD AND
- Documentation stating that psychosocial issues and non-medical interventions are being addressed by the clinical team AND
- The requested dose is NOT greater than FDA recommended maximum daily dosage

**Patients who are >18 years old must have ONE of the following diagnoses:**
- ADHD
- Narcolepsy (for methylphenidate, amphetamine/dextroamphetamine, or dextroamphetamine)
- Cancer-related fatigue (for methylphenidate)
- Fatigue due MS (for methylphenidate)
- Idiopathic hypersomnia (for methylphenidate, amphetamine/dextroamphetamine, or dextroamphetamine)
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| **Afinitor**<sup>[i]</sup>  
Last reviewed: 10/22/2015 | Afinitor may be authorized when the following criteria are met:  
• Prescribed by an oncologist  
• Patient has ONE of the following diagnoses:  
  • Recurrent or stage IV hormone receptor positive (ER/PR +) breast cancer that progressed or recurred while on letrozole or anastrozole:  
    ▪ Patient is postmenopausal OR premenopausal and has had ovarian ablation/suppression  
    ▪ Must be used in combination with exemestane  
  • Pancreatic neuroendocrine tumors (PNET) that are locally advanced, metastatic or unresectable  
  • Tuberous sclerosis complex (TSC) with ONE of the following manifestations:  
    ▪ Renal angiomyolipoma  
    ▪ Subependymal giant cell tumor that is unresectable  
  • Relapsed or stage IV, unresectable, renal cell carcinoma (RCC) of predominant clear cell histology following treatment with a tyrosine kinase inhibitor (i.e., Sutent, Nexavar, Inlyta, or Votrient)  
  • Relapsed or stage IV, unresectable, renal cell carcinoma (RCC) of non-clear cell histology  
| Initial Approval: 1 year  
Renewal: 3 years  
For members with stable disease (tumor size within 25% of baseline).  
Discontinuation is appropriate when there is evidence of disease progression. |
| **Ampyra**<sup>[ii]</sup>  
Last reviewed: 10/22/2015 | May be approved when the following criteria are met:  
• Prescribed by, or in consultation with a neurologist  
• Patient is between 18 and 70 years old  
• Diagnosis of multiple sclerosis with impaired walking ability defined as a baseline 25-ft walking test between 8 and 45 seconds OR Expanded Disability Status Scale (EDSS) between 4.5 and 6.5  
• Patient is stabilized on disease modifying therapy for MS (i.e., no recent exacerbations)  
• Patient is NOT wheelchair-bound  
• Patient does not have a history of seizures  
• Patient does not have moderate to severe renal impairment (Crcl < 50 ml/min)  
| Initial Approval: 2 months  
Renewal: 1 year  
Requires:  
At least 20% improvement in timed walking speeds on 25-ft |
### Antidepressants

**Non-formulary antidepressants can be authorized for patients ≥18 years old who meet ANY of the following criteria:**

- **Patients with treatment resistant depression:**
  - Documented failure or intolerance to THREE formulary agents from at least 2 different classes of antidepressants (SSRI, SNRI, bupropion, or mirtazapine) at an adequate dose and duration (at least 4 weeks).
  - One of these trials must be with a preferred formulary agent from the same class (SSRI or SNRI)
- **Patients who are currently stable on the requested non-formulary antidepressant:**
  - Provider feels that changing to a formulary medication would incur unacceptable risk of destabilization.

**Initial approval:** Indefinite

### ARBs

**Non-preferred ARBs** can be approved for members who have failed THREE formulary preferred ARBs AND meet ONE of the following:

1. Treatment of HTN with chronic kidney disease (CKD); **OR**
2. Treatment of HTN without CKD for patients who have failed a trial with a formulary agent from another class that is considered a first-line treatment per JNC8 (i.e., thiazide-type diuretic, calcium channel blocker, angiotensin-converting enzyme inhibitor) or require combination therapy to achieve BP goal

**Initial Approval:** Indefinite
## Policy Requirements

### Telmisartan

**Preferred ARBs include:**
- Losartan (or losartan/HCTZ)
- Irbesartan (or irbesartan/HCTZ)
- Candesartan (or candesartan/HCTZ)
- Valsartan (or valsartan/HCTZ, valsartan/amlodipine, or valsartan/amlodipine/HCTZ)

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| Telmisartan | Preferred ARBs include:  
- Losartan (or losartan/HCTZ)  
- Irbesartan (or irbesartan/HCTZ)  
- Candesartan (or candesartan/HCTZ)  
- Valsartan (or valsartan/HCTZ, valsartan/amlodipine, or valsartan/amlodipine/HCTZ) |

### Long-Acting Injectable Atypical Antipsychotics

**Non-formulary approval is authorized for members who:**
- Are at least 18 years of age
- Prescribed by or in consultation with a psychiatrist
- Have received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy prior to receiving the long-acting injectable medication
- Will not receive concomitant oral antipsychotics after the initial overlap period (per FDA approved labeling)
- Are not taking a CYP3A4 inducer (Abilify only)
- Have an FDA approved indication:
  - Invega Sustenna/Trinza: schizophrenia or schizoaffective disorder
  - Risperdal Consta: schizophrenia or bipolar I
  - Abilify Maintena: schizophrenia
  - Zyprexa Relprevv: schizophrenia
- Non-adherence to oral antipsychotic medications which places the patient at risk for poor outcomes

**For Illinois:** Invega Sustenna and Risperdal Consta are the formulary preferred agents and are also available without prior authorization for members residing in LTC facilities OR when prescribed by a network psychiatrist

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<tr>
<th>Long-Acting Injectable Atypical Antipsychotics</th>
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<tr>
<td>Invega Sustenna</td>
<td></td>
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</table>
- Preferred ARBs include:  
- Losartan (or losartan/HCTZ)  
- Irbesartan (or irbesartan/HCTZ)  
- Candesartan (or candesartan/HCTZ)  
- Valsartan (or valsartan/HCTZ, valsartan/amlodipine, or valsartan/amlodipine/HCTZ) |

### Botulinum Toxins

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<tr>
<th>Botulinum Toxins</th>
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- Neurogenic bladder (Botox) |
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<tbody>
<tr>
<td>Xeomin</td>
<td>Trial and failure of 2 first-line agents, such as oxybutynin and trospium</td>
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</table>
| Buprenorphine (Subutex), buprenorphine/ naloxone (Suboxone, Zubsolv) | **For patients who meet all of the following:**  
- Age ≥ 16 years old.  
- If request for Suboxone Film, Zubsolv, or Bunavail: member must have had failure of buprenorphine/naloxone sublingual tablets  
- If request for buprenorphine tablets: member must be pregnant or have a true allergy to naloxone  
- Max dose 16 mg/day *(24mg is no longer considered the appropriate dosage except in rare instances that will be considered on a case by case basis)*  
- Prescriber possesses DATA 2000 waiver [Is SAMHSA-certified]  
- Prescribed for management of opioid dependence, not for pain management  
- Attestation from prescriber that the New Jersey Prescription Monitoring Program database has been reviewed for other drug use including benzodiazepines, sedative/hypnotics, and opioids.  
- Documentation supports a comprehensive substance abuse treatment plan including: opioid contract, psychosocial counseling, assessment and treatment of other abuse/dependence behaviors and mental health disorders, and random urine drug screens.  
- Urine drug screen (UDS) completed a maximum of 30 days prior to renewal and is negative for opioids and all controlled substances (e.g., benzodiazepines, amphetamines, illicit drugs, other opioids, including tramadol) and positive for buprenorphine.  
- If UDS is positive for controlled substances, the prescriber must include a treatment plan that addresses tapering/discontinuation of positive substances. | **Initial Approval:**  
3 months  
**Renewal:**  
6 months  
**Documentation required:**  
- UDS results within 30 days prior to renewal and is negative for opioids and all controlled substances (e.g., benzodiazepines, amphetamines, illicit drugs, other opioids, including tramadol) and positive for buprenorphine.  
- If UDS is positive for controlled substances, the prescriber must include a treatment plan that addresses tapering or discontinuation of positive substances. |
## Policy Requirements

- **Caprelsa**
  - Last reviewed: 10/22/15
  - May be authorized for adults when the following criteria are met:
    - Prescribed by an oncologist
    - Patient is at least 18 years old
    - No history of congenital long QT syndrome (Black Box Warning)
    - Patient meets ONE of the following:
      - Diagnosis of locally recurrent or metastatic differentiated thyroid carcinoma (including papillary, follicular, and Hurthle cell) after surgical resection that is progressive or symptomatic AND is refractory to radioactive iodine treatment AND Nexavar or Lenvima
      - Diagnosis of medullary thyroid cancer and one of the following:
        - Local disease progression or recurrence after surgery which is unresectable
        - Symptomatic disease progression or recurrence after surgery with distant metastases
        - Asymptomatic disease progression or recurrence after surgery with distant metastases that is unresectable
  - Initial: 1 year
  - Renewal: 3 years

- **Cambia**
  - Last reviewed: 10/21/15
  - May be authorized for patients who meet the following criteria:
    - Diagnosis of migraine headaches
    - 18 years of age or older
    - Tried and failed at least 2 formulary triptans (e.g., sumatriptan, naratriptan) or has a contraindication to triptans
    - Tried and failed at least 2 formulary NSAIDs (e.g., ibuprofen, naproxen, diclofenac)
  - Initial Approval: Indefinite
  - Limit of 9 packets (1 box per month)

- **Celecoxib**
  - Last reviewed: 10/21/15
  - May be authorized for patients who meet the following criteria:
    - Patient meets ONE of the following:
      - Was unable to achieve clinical benefit with 3 formulary NSAIDs
      - Has a history of NSAID-induced gastritis confirmed by EGD
      - Is at high-risk for adverse GI events (e.g., >65 years of age, concomitant corticosteroid or anticoagulant use, or history of GI bleed, PUD, GERD, or gastritis) AND not currently taking a daily
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<thead>
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| aspirin | - No recent history (in the past 6 months) of acute coronary syndrome (ACS) or CABG  
- Age $\geq$ 2 years old for juvenile rheumatoid arthritis (JRA) OR $\geq$ 18 years old for all other indications  
- Dose does not exceed FDA recommended maximum for indication  
  o OA: 200 mg/day  
  o RA, acute moderate pain, dysmenorrhea, moderate to severe pain associated with orthopedic surgery, ankylosing spondylitis, psoriatic arthritis: 400 mg/day  
  o JRA:  
    - $>25$ kg: 100mg BID  
    - 10-25 kg: 50mg BID | Indefinitely |
| Cimzia | For patients who meet all of the following:  
- Prescribed by, or in consultation with a rheumatologist, dermatologist, or gastroenterologist (based on indication)  
- Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret  
- 18 years of age, or older | Indefinitely |
|        | In addition, for treatment of active ankylosing spondylitis:  
- Failure of, or contraindication/intolerance to all of the following:  
  o Failure of a compliant regimen of two different NSAIDs (or contraindication or intolerance to NSAIDs)  
  o Failure of at least 2 of the following: Enbrel, Humira or Remicade for three consecutive months (or contraindication or intolerance to Enbrel, Humira, and Remicade) | |
|        | In addition, for treatment of moderate to severe active Crohn’s disease:  
- Failure of, or contraindication/intolerance to all of the following:  
  o Oral or IV corticosteroids for one month  
  o Azathioprine OR mercaptopurine for three consecutive months  
  o Parenteral methotrexate for three consecutive months  
  o Humira and Remicade for three consecutive months | |
**AETNA BETTER HEALTH® OF NEW JERSEY**

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| **In addition, for treatment of active psoriatic arthritis:** | - Failure of, or contraindication/intolerance to all of the following:  
  - Methotrexate for at least three months  
  - At least 2 of the following: Enbrel, Humira, or Remicade for three months |  |
| **In addition, for treatment of moderate to severe rheumatoid arthritis:** | - Failure of, or contraindication/intolerance to all of the following:  
  - Methotrexate AND at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) for at least 3 months (in combination or each as monotherapy)  
  - At least 2 of the following: Enbrel, Humira, or Remicade for three consecutive months |  |

**For Patients who meet the following:**
- Prescribed for a medically accepted indication/diagnosis  
- Prescribed by hematologist and/or oncologist, or other specialist per associated diagnosis/indication  

**In addition, for Neupogen:**
- Chemotherapy-induced neutropenia  
  - Chemotherapy regimen has approximately ≥ 20% risk of febrile neutropenia OR  
  - Member is at high-risk for neutropenic complications (e.g., age > 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious comorbidities)  
  - Administered 24 – 72 hours after completion of chemotherapy  
  - Patient is not receiving concurrent chemotherapy and radiation therapy  
- Treatment of neutropenia  
  - Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia  
  - HIV-induced or drug-induced neutropenia in immunosuppressed patients  
    - Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain) OR  
    - Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR  

**Colony-Stimulating Factors (CSF)[i]**
- Last reviewed: 08/14/14  
  - Neupogen  
  - Neulasta  
  - Leukine  

**Initial Approval:**
- **Neupogen**  
  - 14 day course per chemotherapy cycle  
  - Refills if indicated  
- **Neulasta**  
  - 1 dose per 21 days  
  - Refills as indicated  
- **Leukine**  
  - AML, bone marrow transplant: up to 42 days  
  - All other indications: 30 days  

**Renewal:**
- Recent ANC (or platelet count for Neumega)  
- Approval up to 1 year (depending on indication)
### Policy Requirements

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>▪ Patient has a documented bacterial infection</td>
<td></td>
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<tr>
<td>▪ Myeloid reconstitution after autologous or allogenic or autologous bone marrow transplant</td>
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<tr>
<td>▪ Patient has a non-myeloid malignancy</td>
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<tr>
<td>▪ Following reinfusion of peripheral blood stem cells (PBSCs)</td>
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<tr>
<td>▪ <strong>Peripheral blood stem cell (PBSC) mobilization</strong></td>
<td></td>
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<tr>
<td>▪ Prior to and during leukopheresis in cancer patients preparing to undergo bone marrow ablation</td>
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<tr>
<td><strong>In addition, for Neulasta:</strong></td>
<td></td>
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<tr>
<td>▪ <strong>Chemotherapy-induced neutropenia</strong></td>
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<tr>
<td>▪ Chemotherapy regimen has approximately ≥ 20% risk of febrile neutropenia</td>
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<tr>
<td>▪ Chemotherapy cycle is at least 14 days</td>
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<tr>
<td>▪ Neulasta will NOT be administered in the following situations:</td>
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<tr>
<td>▪ In the period between 14 days before and 24 hours after completion of chemotherapy</td>
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<td>▪ Concurrently with radiation therapy</td>
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<tr>
<td>▪ Concurrently with mitomycin C</td>
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<tr>
<td>▪ Concurrently with antimetabolites (e.g., 5-FU, cytarabine)</td>
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<tr>
<td>▪ Concurrently with agents that have a delayed myelosuppressive effect (e.g., nitrosureas)</td>
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<tr>
<td><strong>In addition, for Leukine:</strong></td>
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<tr>
<td>▪ <strong>Chemotherapy-induced neutropenia</strong></td>
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<tr>
<td>▪ AML</td>
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<tr>
<td>▪ Patient must be at least 55 years old</td>
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<tr>
<td>▪ Bone marrow is hypoplastic with &lt; 5% blasts (<em>contraindicated in patients with excessive leukemic blasts (≥ 10%) in the bone marrow or peripheral blood</em>)</td>
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<td>▪ Administered on day 11 (or 4 days after the completion) of induction therapy</td>
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<tr>
<td>▪ All other malignancies</td>
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<tr>
<td>▪ Administered at least 24 hours after the completion of chemotherapy</td>
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<tr>
<td>▪ <strong>Treatment of neutropenia</strong></td>
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</tbody>
</table>
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<thead>
<tr>
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<tbody>
<tr>
<td>o Bone marrow transplant failure or engraftment delay</td>
<td></td>
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<tr>
<td>o Myeloid reconstitution after allogenic or autologous bone marrow transplant</td>
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<tr>
<td>▪ Patient has Hodgkin’s disease, non-Hodgkin’s lymphoma, or acute lymphocytic leukemia</td>
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<tr>
<td>o Before and after peripheral blood stem cell transplantation</td>
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<tr>
<td>o Following reinfusion of peripheral blood stem cells (PBSCs)</td>
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<tr>
<td>o HIV-induced or drug-induced neutropenia in immunosuppressed patients</td>
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<tr>
<td>▪ Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain) OR</td>
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<tr>
<td>▪ Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR</td>
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<tr>
<td>▪ Patient has a documented bacterial infection</td>
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<tr>
<td>• Peripheral blood stem cell (PBSC) mobilization</td>
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<tr>
<td>o Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation</td>
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<tr>
<td>• Patient is not a neonate</td>
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<tr>
<td>• Patient is not receiving concurrent chemotherapy and radiation</td>
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- CSFs for non-FDA approved indications require medical literature/clinical studies from peer-reviewed journals with safety, efficacy and dosing information for the intended use.

### Cometriq

**May be authorized when the following criteria are met:**

- Prescribed by an oncologist
- Patient is at least 18 years old
- Documented diagnosis of medullary thyroid cancer AND ONE of the following:
  - Local disease progression or recurrence after surgery which is unresectable
  - Symptomatic disease progression or recurrence after surgery with distant metastases
  - Asymptomatic disease progression or recurrence after surgery with distant metastases that is unresectable

**Initial:** 1 year  
Recommended dose: 140 mg ORALLY once daily

**Renewal:** 3 years  
Discontinuation is appropriate upon disease progression or drug toxicity
### Policy

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<tr>
<td>Compounds</td>
<td><strong>Compounds are not a covered benefit with the following exceptions:</strong></td>
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<td></td>
<td>• Use in pediatric patients under the age of 6</td>
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<tr>
<td></td>
<td>• Use of 17-alpha hydroxyprogesterone caproate when medically necessary for the prevention of preterm birth in women who are pregnant with a singleton pregnancy and have history of a prior spontaneous preterm birth.</td>
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<td></td>
<td>• If a patient has an allergy and requires a medication to be compounded without a certain active ingredient (e.g. dyes, preservatives, fragrances). This situation requires submission of an FDA MedWatch form consistent with DAW1 guidelines.</td>
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<td></td>
<td>• If a patient cannot consume the medication in any of the available formulations and the medication is medically necessary (i.e., unable to swallow).</td>
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<td></td>
<td>• If the prescription product is unavailable due to a market shortage and it is medically necessary.</td>
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<td></td>
<td><strong>NOTE:</strong> Compounds for 17-alpha hydroxyprogesterone caproate should process at the point of sale without a rejection. All compounds for pediatric patients under the age of 6 are covered. All other prescriptions for compounds will require a PA.</td>
<td></td>
</tr>
</tbody>
</table>

Coverage is not provided for compounds applied topically that contain ingredients that are not FDA-approved for topical use (i.e., gabapentin, cyclobenzaprine, baclofen).

### Fibrosis (pulmonary) Medications

<table>
<thead>
<tr>
<th>Pulmozyme: Cystic</th>
<th>Initial Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;/= 5 years (Per label: Pulmozyme was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients &lt;5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.</td>
<td>Indefinite</td>
</tr>
</tbody>
</table>
### Tobramycin inhalation solution (generic for Tobi):

- Diagnosis of cystic fibrosis
- Age $\geq 6$ years
- FEV$_1$ between 25-80% predicted
- Sputum cultures positive for *P. aeruginosa*
  - NOT colonized with *Burkholderia cepacia*

### Tobi Podhaler or Bethkis:

- Must meet criteria listed above for tobramycin inhalation solution, **PLUS** patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic)

### Cayston will be authorized for patients that meet the following:

- Diagnosis of cystic fibrosis
- Age $\geq 7$ years
- FEV$_1$ between 25-75% predicted
- Sputum cultures positive for *P. aeruginosa*
- NOT colonized with *Burkholderia cepacia*
- Contraindication/intolerance to tobramycin

### Kalydeco can be recommended for approval for patients who meet the following:

- Diagnosis of cystic fibrosis with one of the following CFTR gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H
### AETNA BETTER HEALTH® OF NEW JERSEY

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Daliresp</strong></td>
<td></td>
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<tr>
<td></td>
<td><strong>For patients who meet all of the following:</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td>• Adult 40 years of age or older</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>• Prescribed by or in consultation with a pulmonologist</td>
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<tr>
<td></td>
<td>• Diagnosis of severe COPD with chronic bronchitis with FEV1&lt;50% predicted based on post-bronchodilator FEV1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documented symptomatic exacerbations within the last year while compliant with dual long-acting bronchodilator treatment [long-acting beta-agonist (LABA) plus long-acting muscarinic antagonist (LAMA)] for at least 3 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Daliresp will be used in conjunction with a LABA and LAMA unless contraindicated/intolerant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will not be used in combination with theophylline</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Januvia, Janumet, and Janumet XR are available after step-therapy (ST) with trial and failure of metformin.</strong></td>
<td><strong>Indefinitely</strong></td>
</tr>
<tr>
<td></td>
<td><strong>All other DPP-IV inhibitors:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trial and failure, or contraindication to Januvia or Janumet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Age restriction: must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Direct Renin Inhibitors</strong></td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>For patients that meet the following:</strong></td>
<td><strong>Indefinite</strong></td>
</tr>
<tr>
<td></td>
<td>• Treatment of HTN</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inadequate response or inability to tolerate a trial of a formulary ARB and ACE inhibitor and at least one</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- **Not homozygous for the F508del mutation in the CFTR gene**
- **Age >/=2 years**
- **Note: all reviews must be sent to MDR for final decision**
# AETNA BETTER HEALTH® OF NEW JERSEY

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</thead>
</table>
| Tekamlo / Amturnide     | other formulary antihypertensive agent from a different class:  
  - Thiazide-type diuretic  
  - Calcium channel blocker  
  - Beta-blocker  
  - Will not be used in combination with an ACE inhibitor or an ARB  
  - Note: The long-term benefit on major cardiovascular or renal outcomes with direct renin inhibitors in the treatment of HTN has not been established, therefore it is recommended to use medications from other classes first. |                                             |
| Duavee                  | Duavee can be approved for adult women who have an intact uterus and who meet ONE of the following:  
  - Treatment of vasomotor symptoms associated with menopause (VMS):  
    - Patient has failed (or has contraindication/intolerance to) at least 2 formulary estrogen/progestin products (e.g., estradiol tablets/patch, Prempro, Estrace)  
  - Prevention of postmenopausal osteoporosis:  
    - Patient is at significant risk of osteoporosis  
    - Patient has tried and failed (or has contraindication/intolerance to) raloxifene and alendronate (non-estrogen medication is preferred) | Initial Approval:  
  - 5 years |
|                         | o Eyelid or other sensitive area – Elidel will be approved without trial and failure of topical corticosteroids  
  - Protopic is covered after trial and failure of Elidel |                                             |
| Enbrel, Humira          | For Patients who meet the following:  
  - Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist)  
  - Additional criteria based on the diagnosis (unless contraindications are documented):  
    - Ankylosing Spondylitis:  
      - Trial and failure of 2 different NSAIDs within the last 60-days  
      - Age restriction: must be at least 18 years old  
    - Plaque Psoriasis: | Initial Approval:  
  - Enbrel:  
    - Plaque psoriasis: 3 months  
      (dose: 50mg twice weekly)  
  - Humira: |
### Policy Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
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</tr>
</thead>
<tbody>
<tr>
<td>▪ Trial and failure of UVB or PUVA therapy or contraindication to therapy</td>
<td>・ Ulcerative Colitis: 3 months (discontinue Humira if remission is not seen by week 8)</td>
</tr>
<tr>
<td>▪ Trial and failure of methotrexate for at least 3 consecutive months or contraindication/intolerance to methotrexate</td>
<td>Other indications: Indefinitely</td>
</tr>
<tr>
<td>▪ Psoriatic Arthritis:</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of a compliant regimen of methotrexate for at least 3 months</td>
<td></td>
</tr>
<tr>
<td>▪ Age restriction: must be at least 18 years old</td>
<td></td>
</tr>
<tr>
<td>▪ Rheumatoid Arthritis (Adults):</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)</td>
<td></td>
</tr>
<tr>
<td>▪ JIA (age ≥ 2 years for Enbrel, ≥ 4 years for Humira):</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of at least 3 consecutive months of methotrexate or contraindication/intolerance to methotrexate</td>
<td></td>
</tr>
<tr>
<td>▪ Crohn’s Disease (Humira only):</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of oral or intravenous corticosteroids for at least one month</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of a 3-month compliant regimen of azathioprine or mercaptopurine</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of parenteral methotrexate OR</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of Remicade</td>
<td></td>
</tr>
<tr>
<td>▪ Age restriction: must be at least 6 years old</td>
<td></td>
</tr>
<tr>
<td>▪ Ulcerative Colitis (Humira only):</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of a compliant regimen of oral or rectal aminosalicylates (e.g., mesalamine, sulfasalazine) for 2 consecutive months or contraindication/intolerance to aminosalicylates</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of oral or intravenous corticosteroids for at least one month</td>
<td></td>
</tr>
<tr>
<td>▪ Trial and failure of a 3-month compliant regimen of azathioprine or mercaptopurine or contraindication/intolerance to azathioprine and mercaptopurine</td>
<td></td>
</tr>
<tr>
<td>Policy</td>
<td>Requirements</td>
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</tr>
</tbody>
</table>
| Entyvio\textsuperscript{v} | For patients that meet all of the following:  
• At least 18 years old  
• Prescribed by, or in consultation with a gastroenterologist  
• Recommended immunizations are current before initiating treatment  
  
In addition, for moderate to severe active Crohn's disease:  
• Patient has tried and failed corticosteroids (oral or IV) for 1 month  
• Patient has failed a 3-consecutive month trial of azathioprine or mercaptopurine  
• Patient has failed a 3-consecutive month trial of Humira or Remicade  
  o If patient has contraindication/intolerance to any of these medications, that requirement will be waived  
  
In addition, for moderate to severe active ulcerative colitis:  
• Patient has failed a 2-consecutive month trial of oral or rectal aminosalicylates (i.e., mesalamine, sulfasalazine)  
• Patient has failed a one month trial and failure of corticosteroids (oral or IV)  
• Patient has failed a 3-consecutive month trial of azathioprine or mercaptopurine  
• Patient has failed a 2-consecutive month trial and failure of Humira or Remicade  
If patient has contraindication/intolerance to any of these medications, that requirement will be waived | Initial Approval:  
4 months  

Renewal:  
1 year  
Requires: Response to treatment |
| Epanova\textsuperscript{v} | For patients that meet the following:  
• At least 18 years old  
• On an appropriate lipid-lowering diet and exercise regimen  
• Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL)  
Trial and failure of OTC fish oil and at least ONE other formulary medication such as fenofibrate, fenofibric acid, gemfibrozil, or OTC niacin or contraindication to all formulary agents | Initial Approval Indefinite |
# AETNA BETTER HEALTH® OF NEW JERSEY

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</table>
| Erythropoiesis-Stimulating Agents (ESA) | **Anemia Due to CKD (Epogen, Procrit, Aranesp)**  
- Hemoglobin < 10 g/dL within the last 2 weeks  
- Iron studies showing member has adequate iron stores to support erythropoiesis (e.g., ferritin >100, transferrin saturation >20%)  
**Anemia Due to Peg-Interferon and Ribavirin Treatment for Hepatitis C (Epogen, Procrit, Aranesp)**  
- Recent (within the last 2 weeks) hemoglobin 8.5-10 g/dL (if hemoglobin < 8.5, hep C treatment should be discontinued)  
  AND  
- Member was unresponsive to ribavirin dosage reduction  
  OR  
- Member has HIV co-infection, cirrhosis, or liver transplant  
- Age restriction: Safety and efficacy in neonates has not been established. | **Initial Approval:**  
- Anemia due to CKD in patient receiving dialysis not enrolled with Medicare Part B: 4 months to allow time for enrollment with Medicare Part B for dialysis coverage  
- Reduction of Allogenic Blood Transfusion in Surgery Patients: up to 21 days of therapy per surgery  
- Anemia Due to Pegylated Interferon and Ribavirin Treatment for Hepatitis C: 1 month  
- All other indications: 3 months |
| Epogen, Procrit, Aranesp | **Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery (Epogen, Procrit)**  
- Patient will be undergoing elective, noncardiac, nonvascular surgery  
- Hemoglobin level >10 and < 13 g/dL within 30 days prior to the planned surgery date  
**Anemia Due to Zidovudine in HIV-infected Patients (Epogen, Procrit)**  
- Patient is receiving treatment with zidovudine at a dose < 4200 mg/week  
- Patient meets both of the following:  
  - Endogenous erythropoietin levels < 500 mUnits/mL. | **Renewal:**  
- 3 months  
**Documentation Required:** Hb < 11 g/dL within the last 2 weeks. Follow up iron studies showing member has adequate iron to support erythropoiesis |
### AETNA BETTER HEALTH® OF NEW JERSEY

#### Policy Requirements

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</tr>
</tbody>
</table>

**Anemia associated with myelodysplastic syndrome**  
(*Epogen, Procrit*)

- Patient meets all of the following:
  - Hemoglobin < 10 g/dL within 2 weeks prior to initiating therapy
  - Recent erythropoietin level < 500 mU/mL

**Anemia due to Chemotherapy in Patients with Cancer**  
(*Epogen, Procrit, Aranesp*)

- Patient is currently receiving chemotherapy
- Patient meets all of the following:
  - Hemoglobin < 10 g/dL within the 2 weeks prior to starting therapy
  - Documentation to support anemia is due to concomitant myelosuppressive chemotherapy
  - Diagnosis of non-myeloid malignancy (e.g., solid tumor)

Patient has a minimum of 2 additional months of planned chemotherapy upon initiation of therapy. Additional information may be required on a case-by-case basis to allow for adequate review.

**Forteo**

For Patients who meet all of the following:

- Adult > 18 years of age
- **Black box warning** – due to the potential risk of osteosarcoma, Forteo should not be used in patients at increased baseline risk for osteosarcoma (e.g., Paget’s disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton). Forteo should only be prescribed for patients whom potential benefits outweigh potential risk.

**For the treatment of osteoporosis in men and women who meet the following criteria:**

- Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate) **OR**

**Initial Approval:**

- Osteoporosis – 2 years
- Hypoparathyroidism – 3 months (parathyroid hormone level, PTH – within 30 days)

**Renewal:**

- 1 year
- Parathyroid hormone level, PTH (hypoparathyroidism)
## AETNA BETTER HEALTH® OF NEW JERSEY

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</thead>
<tbody>
<tr>
<td>Glucagon-like Peptide-1 agonists</td>
<td>Byetta is available after step-therapy (ST) with trial and failure of metformin for members age 18 or older</td>
<td>Indefinitely</td>
</tr>
<tr>
<td><strong>GnRH Analogs</strong>[vi]</td>
<td>For patients who meet the following based on diagnosis:</td>
<td><strong>Initial Approval:</strong></td>
</tr>
<tr>
<td>Last reviewed: 7/1/15</td>
<td><strong>Endometriosis</strong></td>
<td><strong>Central Precocious Puberty</strong></td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td><strong>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</strong></td>
<td>• Supprelin LA: 12 months</td>
</tr>
<tr>
<td>Lupon Depot Lupon Depot-PED</td>
<td>• Prescribed by or in consultation with a gynecologist or obstetrician</td>
<td>• All others: 6 months</td>
</tr>
<tr>
<td>Eligard</td>
<td>• 18 years of age or older</td>
<td><strong>Endometriosis</strong></td>
</tr>
<tr>
<td>Treistar</td>
<td>• Trial and failure of at least one formulary hormonal cycle control agent</td>
<td>• 6 months</td>
</tr>
<tr>
<td>Vantas</td>
<td>(such as Portia, Ocella, Previmem), medroxyprogesterone, or Danazol</td>
<td><strong>Uterine Leiomyoma (fibroids)</strong></td>
</tr>
<tr>
<td>Synarel</td>
<td>• Patient is not pregnant or breastfeeding</td>
<td>• 6 months</td>
</tr>
<tr>
<td>Supprelin LA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Uterine Leiomyoma (fibroids)

**Zoladex**
- Prescribed by or in consultation with a gynecologist or obstetrician
- 18 years of age or older
- Prescribed to improve anemia and/or reduce uterine size for 3-6 months prior to planned surgical intervention
- Patient is not pregnant or breastfeeding

## Dysfunctional Uterine Bleeding

**Zoladex [3.6 mg dose only]**
- Prescribed by or in consultation with a gynecologist or obstetrician
- 18 years of age or older
- Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks
- Patient is not pregnant or breastfeeding

## Central Precocious Puberty (CPP)

**Zoladex (Lupron Depot-PED, leuprolide acetate solution, Synarel, Supprelin LA)**
- Prescribed by, or in consultation with an Endocrinologist
- MRI or CT Scan has been performed to rule out lesions
- Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males
- Response to a GnRH stimulation test (or if not available, other labs to support CPP such as luteinizing hormone levels, estradiol and testosterone level)
- Bone age advanced 1 year beyond the chronological age
- Baseline height and weight
- Age restriction (leuprolide acetate solution for injection [once daily regimen]): must be at least 1 year old
- Age restriction (Lupron Depot-Ped [1-month or 3-month regimen]): must be at least 2 years old
- Bone mineral density within normal limits
- Use in combination with norethindrone acetate

## Advanced Prostate Cancer

**Zoladex (Lupron Depot, Leuprolide acetate solution, Eligard, Zoladex, Vantas Trelstar)**
- 2 months
- 2 years
- 6 months - 1 year (up to age 11 for females and age 12 for males)
- Requires clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level)
- Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months): 6 months
- Requires:
  - Bone mineral density within normal limits
  - Use in combination with norethindrone acetate
## AETNA BETTER HEALTH® OF NEW JERSEY

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</thead>
<tbody>
<tr>
<td><strong>Gonadotropin-Releasing Hormone Agonists</strong> (GnRH Analogs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leuprolide, Lupron Depot/Depot-PED, Eligard, Supprelin LA, Synarel, Zoladex, Vantus, Trelstar</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Advanced Breast Cancer** *(Zoladex [3.6mg dose only]*) | • Prescribed by, or in consultation with oncologist or urologist  
• Age restriction: must be at least 18 years old | • Long-term use is not recommended  
• Retreatment may be considered on a case by case basis |
| **Endometriosis** *(Lupron Depot, Synarel, Zoladex (3.6mg dose only))* | For patients who meet the following based on diagnosis:  
**Endometriosis** *(Lupron Depot, Synarel, Zoladex (3.6mg dose only))*  
For patients who meet all of the following:  
• Prescribed by or in consultation with a gynecologist or obstetrician  
• 18 years of age or older  
• Diagnosis of Endometriosis  
• Trial and failure of at least one formulary hormonal cycle control agent such as Portia, Ocella, Preivem, medroxyprogesterone or Danazol | **Initial Approval:**  
• Central Precocious Puberty (CPP) or Endometriosis:  6 months; for Supprelin LA in CPP: 1 year  
• Uterine Leiomyomata (fibroids): Lupron-3 months, Zoladex, Synarel-6 months  
• Prostate Cancer: indefinite |
| **Uterine Leiomyomata (fibroids)** *(Lupron Depot, Synarel, Zoladex 3.6mg)* | For patients who meet all of the following:  
• Prescribed by or in consultation with a Gynecologist or Obstetrician  
• 18 years of age or older  
• Preoperative surgical intervention (within 3-6 months) | **Renewal:**  
• Central Precocious Puberty (CPP):  
  o 6 months – 1 year up to age 11 for females and age 12 for males  
  o clinical response to treatment (i.e., prepubertal slowing or decline, FSH, LH, Bone Age, or estradiol and testosterone level)  
• Endometriosis Retreatment:  
  o Lupron only (treatment
### Central Precocious Puberty (CPP) (Lupron Depot-PED, leuprolide acetate, Synarel, Supprelin LA)

**For patients who meet all of the following:**
- Prescribed by, or in consultation with an Endocrinologist
- Diagnosis of CPP
- MRI or CT Scan has been performed to rule out lesions
- Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males
- Response to a GnRH stimulation test (or if not available, other labs to support CPP such as luteinizing hormone levels, estradiol, and testosterone level)
- Bone age advanced 1 year beyond the chronological age
- Baseline height and weight
- Age restriction (leuprolide acetate solution for injection [once daily regimen]): must be at least 1 year old
- Age restriction (Lupron Depot-Ped [1-month or 3-month regimen]): must be at least 2 years old

### Advanced Prostate Cancer (Lupron Depot, leuprolide acetate, Eligard, Zoladex, Vantas, Trelstar)

- Prescribed by, or in consultation with Oncologist or Urologist
- Diagnosis of prostate cancer
- Age restriction: must be at least 18 years old

### Advanced Breast Cancer (Zoladex: 3.6mg dose only)

- Prescribed by, or in consultation with Oncologist
- Diagnosis of breast cancer
- Age restriction: must be at least 18 years old

### Duration of approval if requirements are met

- with Synarel and Zoladex not recommended beyond 6 months): One 6 month course (up to 1 year of treatment)
  - Member must be using in combination with norethindrone acetate 5 mg daily
  - Requires bone density values (DEXA OR BMD) within normal limits

### Uterine Leiomyomata (fibroids):

The recommended duration of treatment is \( \leq 3 \) months. Retreatment may be considered on a case by case basis.
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Growth Hormone</td>
<td>See detailed document: <a href="https://aetsp10.aetna.com/sites/medicaidhub/ss/rx/Pharmacy%20PA%20Guidelines/Growth%20Hormone.docx">https://aetsp10.aetna.com/sites/medicaidhub/ss/rx/Pharmacy%20PA%20Guidelines/Growth%20Hormone.docx</a></td>
<td>Initial:</td>
</tr>
<tr>
<td>Genotropin</td>
<td></td>
<td>Pediatric Indications: 6 months</td>
</tr>
<tr>
<td>Humatrope</td>
<td></td>
<td>Adult GHD: 6 months</td>
</tr>
<tr>
<td>Norditropin</td>
<td></td>
<td>Adults with wasting due to HIV: 3 months</td>
</tr>
<tr>
<td>Nutropin</td>
<td></td>
<td>Adults with SBS: one four-week course of therapy</td>
</tr>
<tr>
<td>Omnitrope</td>
<td></td>
<td>Adults with excess abdominal fat in HIV-infected patients with lipodystrophy (Egrifta®): 3 months</td>
</tr>
<tr>
<td>Saizen</td>
<td></td>
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<tr>
<td>Tev-Tropin</td>
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<tr>
<td>Zorbtive</td>
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<tr>
<td>Adults with SBS: one four-week course of therapy</td>
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</tr>
</tbody>
</table>

**Initial:**

- **Pediatric Indications**: 6 months
- **Adult GHD**: 6 months
- **Adults with wasting due to HIV**: 3 months
- **Adults with SBS**: one four-week course of therapy
- **Adults with excess abdominal fat in HIV-infected patients with lipodystrophy (Egrifta®)**: 3 months

**Renewal:**

- **Pediatric Indications** - 6 months
  - Documentation to support final height has not been achieved, no evidence of epiphyseal closure, AND growth velocity is > 5cm/year on current dose or < 5 cm/year with intended dose increase
## Policy Requirements

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<th>Policy</th>
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<th>Duration of approval if requirements are met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>o For Prader Willi Syndrome: documentation to show body composition (e.g. ratio of lean to fast muscle) has improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o For Chronic Renal Insufficiency: there is insufficient data regarding the benefit of treatment beyond three years</td>
</tr>
</tbody>
</table>

### Adult Indications:

- **Adults with GHD**: 6 months if IGF-1 is low but dose is being increased or 1 year if IGF-1 is at a stable range
- **Adults with wasting due to HIV (Serostim)**: 12 weeks (maximum 48 weeks)
  - Documentation to support response to therapy
- **Adults with SBS (Zorbtive)**: Approve 4 weeks, No renewals
- **Adults with excessive abdominal fat in HIV-infected patients with lipodystrophy (Egrifta)**: 6 months
# AETNA BETTER HEALTH® OF NEW JERSEY

<table>
<thead>
<tr>
<th>Policy</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Hetlioz™</strong>&lt;br&gt;Last reviewed: 4/22/15</td>
<td>For patients that meet all of the following:&lt;br&gt;• At least 18 years old&lt;br&gt;• Diagnosis of non-24 sleep-wake disorder&lt;br&gt;• Completely blind with NO light perception&lt;br&gt;• History of at least 3 months of difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness&lt;br&gt;• No other concomitant sleep disorder (i.e., sleep apnea, insomnia)</td>
<td><strong>Initial Approval</strong>&lt;br&gt;Indefinite</td>
</tr>
<tr>
<td><strong>Hyaluronic Acid Agents (Topical)</strong>&lt;br&gt;Last reviewed: 09/22/2015&lt;br&gt;Topical:</td>
<td>When used for treatment of osteoarthritis of the knee, the following criteria must be met:&lt;br&gt;• Patient must be at least 18 years of age&lt;br&gt;• Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, bone-on-bone, osteophytes) or Grade 1-3 degenerative joint disease&lt;br&gt;• Trial and failure or contraindications to conservative non-pharmacologic therapy (physical therapy,</td>
<td><strong>Injection:</strong> <strong>Initial Approval:</strong>&lt;br&gt;1 series of injections per knee every 6 months</td>
</tr>
</tbody>
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### AETNA BETTER HEALTH® OF NEW JERSEY

<table>
<thead>
<tr>
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</thead>
</table>
| **Bionect**  
**HyGel**  
**HyliRa**  
**XClair** | weight loss)  
- Trial and failure or contraindications to simple analgesics, including NSAIDs and acetaminophen  
- Trial and failure of intra-articular steroid treatment, if applicable |  
**Renewal:**  
- 1 series of injections per knee every 6 months  
**Initial Approval:**  
- **Burns or dermatitis:**  
  - 3 fills of generic agent  
- **Xerosis:**  
  - Up to 1,000 grams of equivalent generic agent per 30 days for three months  
**Renewal:**  
- 3 months |
| **Hyperlipidemia Medications**[^vi] | **Crestor can be approved when the following criteria are met:**  
- Patient is at least 10 years old; **AND**  
- Patient has failed to achieve LDL goal on a compliant regimen of maximum tolerated dose of atorvastatin; **OR**  
- Patient requires a high intensity statin (i.e., diagnosis of familial hypercholesterolemia or high ASCVD risk per provider evaluation) AND patient had a trial and failure of atorvastatin |  
**PSCK9 inhibitors:**  
- Juxtapid, Kynamro: 3 months  
- All others: 6 months  
**Renewal:**  
- PSCK9 inhibitors: 6 months  
- Juxtapid, Kynamro: 6 months  
- All others: indefinite  
**Renewals require improvement in fasting lipids and documentation of recommended safety monitoring parameters (such as liver enzymes)** |
| **Zetia**  
**Lovaza**  
**Vascepa**  
**Epanova**  
**Repatha**  
**Praluent**  
**Juxtapid** | **Zetia requires step therapy:**  
- If member has filled 2 prescriptions for 2 different statins (specifically atorvastatin, simvastatin or Crestor) within the last 130-days, the prescription will automatically process at the pharmacy.  
- Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.  
- In those cases, Zetia will be authorized upon receipt of documentation to support the diagnosis of hyperlipidemia and failure of, or contraindication to atorvastatin, simvastatin, and Crestor.  
Non-formulary medications for hypertriglyceridemia (Lovaza, Vascepa, and Epanova) can be approved when |  
**Initial Approval:**  
- Juxtapid, Kynamro: 3 months  
- All others: 6 months  
**Renewal:**  
- Juxtapid, Kynamro: 6 months  
- All others: indefinite  
**Renewals require improvement in fasting lipids and documentation of recommended safety monitoring parameters (such as liver enzymes)** |

[^vi]: Last reviewed: 6/15/15
### AETNA BETTER HEALTH® OF NEW JERSEY

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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<tbody>
<tr>
<td><strong>Kynamro</strong></td>
<td><strong>the following criteria are met:</strong></td>
<td></td>
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<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
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<td></td>
<td>• Drug will be used as an add-on to lifestyle interventions to include diet and exercise</td>
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<td></td>
<td>• Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL)</td>
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<td></td>
<td>• Trial and failure of OTC fish oil and at least ONE other formulary medication such as fenofibrate, fenofibric acid, gemfibrozil, or niacin</td>
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<td></td>
<td>or contraindication to all formulary agents</td>
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<tr>
<td><strong>PCSK9 Inhibitors (Repatha and Praluent) can be approved when ALL of the following criteria are met:</strong></td>
<td></td>
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<td></td>
<td>• Lab results support an LDL ≥300 mg/dL (within the past 90 days)</td>
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<td></td>
<td>• Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and Crestor) at maximum tolerated doses used in combination with Zetia, niacin, or a bile acid sequestrant</td>
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<tr>
<td></td>
<td>• The PCSK9 will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant</td>
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<td></td>
<td>• In addition for diagnosis of Familial Hypercholesterolemia (FH):</td>
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<td></td>
<td>o Patient has tried and failed or is not a candidate for LDL apheresis</td>
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<td></td>
<td>• In addition for diagnosis of Primary Hypercholesterolemia non FH:</td>
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<td>o Chart notes support evidence of ASCVD or high CVD risk (i.e., history of AMI, MI, PCI, or CABG)</td>
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<td></td>
<td>• NOTE: All requests must be forwarded to MDR for final approval</td>
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<tr>
<td><strong>Juxtapid and Kynamro can be approved when ALL of the following criteria are met:</strong></td>
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<tr>
<td></td>
<td>• Diagnosis of homozygous familial hypercholesterolemia with a documented LDL of ≥300 mg/dl (within the past 90 days)</td>
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<tr>
<td></td>
<td>• Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and Crestor) at maximum tolerated doses used in combination with Zetia, niacin, or a bile acid sequestrant</td>
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<tr>
<td></td>
<td>• Juxtapid or Kynamro will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant AND lifestyle interventions to include diet and exercise (low-fat diet recommended, &lt;20% of calories from fat)</td>
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<tr>
<td></td>
<td>• Patient has tried and failed or is not a candidate for LDL apheresis</td>
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<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
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<tr>
<td></td>
<td>• Recommended baseline labs are submitted: Fasting lipid panel, ALT, AST, alk phos, total bili, and negative pregnancy test (if applicable)</td>
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### AETNA BETTER HEALTH® OF NEW JERSEY

**Policy Requirements**

<table>
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<tr>
<th>Duration of approval if requirements are met</th>
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<tbody>
<tr>
<td><strong>Initial Approval:</strong> 6 months</td>
</tr>
<tr>
<td><strong>Renewal:</strong> 6 months if at least doubling of pretreatment growth velocity, 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open</td>
</tr>
</tbody>
</table>

**For patients that meet the following:**

- Prescribed by or in consultation with pediatric endocrinologist
- Patient is ≥ 2 years old
- No evidence of epiphyseal closure
- No evidence of neoplastic disease
- Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency
  - Height standard deviation score less than or equal to -3
  - Basal IGF-1 standard deviation score less than or equal to -3
  - Normal or elevated growth hormone (GH) levels
  - No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids.
  - OR
- Documentation supports diagnosis of GH gene deletion and development of neutralizing antibodies to GH

---

### Esbriet

- **Non-formulary use of Esbriet or Ofev can be approved when the following are met:**
  - Diagnosis of mild to moderate idiopathic pulmonary fibrosis
    - Confirmed by high resolution computed tomography (HRCT), lung biopsy, or bronchoscopy
    - Interstitial lung disease cannot be attributed to another cause (i.e., rheumatoid arthritis, lupus, systemic sclerosis, asbestos exposure, or hypersensitivity pneumonitis)
    - Forced vital capacity (FVC) between 50 and 80% predicted
  - Documentation of baseline liver function tests (LFT’s) prior to initiating treatment
  - Patient age must be 18 years or greater
  - Patient is not a current smoker

- **Initial Approval:** 3 months
- **Renewal:** 6 months

Criteria for renewal:
- Documentation of stable FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)
### Anticoagulants - Injectable

Last reviewed: 10/21/2015

<table>
<thead>
<tr>
<th>Enoxaparin</th>
<th>Fondaparinux</th>
<th>Fragmin</th>
<th>Iprivask</th>
</tr>
</thead>
</table>

Fragmin, fondaparinux, and enoxaparin should pay at the point of sale for an initial duration without a PA.

**Note:** There is no conclusive evidence to support the use of any drugs to increase the survival of people with idiopathic pulmonary fibrosis.

**Requirements**

- Prescribed by, or in consultation with, a pulmonologist

**Duration of approval if requirements are met**

- Attestation that LFT’s are being monitored

**Initial Approval:**

- **Prophylaxis post ortho surgery**
  - Up to 35 days
- **Prophylaxis (non-ortho surgery and major trauma)**
  - Up to 14 days
- **Prophylaxis (post-surgery with CA)**
  - 4 weeks
- **VTE treatment, bridge therapy, acute illness**
  - 10 days or as requested
- **High risk pregnancy**
  - Until 6 weeks after delivery (EDC required for authorization)
- **Prophylaxis in cancer**

---

For prescriptions of enoxaparin, fondaparinux, and Fragmin that do not pay at the point of sale, prior authorization requests can be authorized for the following indications:

- **All 3 agents:**
  - VTE prophylaxis in patients undergoing hip or knee replacement or hip fracture surgery
  - VTE treatment in patients who are taking warfarin until the INR is in therapeutic range for 2 days
  - Bridge therapy for perioperative warfarin discontinuation
  - Prophylaxis or treatment of thrombotic complications in a high risk pregnancy
  - VTE prophylaxis in patients with restricted mobility during acute illness
  - Treatment of superficial vein thrombosis (SVT) of the lower limb of at least 5 cm in length
  - Treatment of acute upper-extremity DVT (UEDVT) that involves the axillary or more proximal veins

- **Fragmin and enoxaparin only:**
  - VTE treatment after trial and failure of warfarin or for patients who are not candidates for warfarin
  - VTE treatment in patients who have cancer
  - VTE prophylaxis in cancer patients with solid tumors who are at high risk of thrombosis (i.e., previous VTE, immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, and lenalidomide)
  - VTE prophylaxis in patients with AFib undergoing cardioversion (up to 3 weeks before and 4 weeks after)
  - VTE prophylaxis in patients with acute ischemic stroke and restricted mobility
  - VTE prophylaxis in patients undergoing general and abdominal-pelvic surgery who are at moderate to high risk for VTE
  - VTE prophylaxis in patients with major trauma
### AETNA BETTER HEALTH® OF NEW JERSEY

**Injectable Osteoporosis Agents**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Prolia</td>
<td>For patients who meet all of the following:</td>
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<tr>
<td></td>
<td>• Adult &gt; 18 years of age</td>
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<tr>
<td>Reclast</td>
<td>For the treatment of osteoporosis in members who meet the following criteria:</td>
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<tr>
<td></td>
<td>• Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate)</td>
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<td></td>
<td>• Failure of a 6 month trial of a formulary oral bisphosphonate</td>
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<td>OR</td>
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- **Iprivask may be authorized if all the following criteria are met:**
  - VTE prophylaxis in patients undergoing hip replacement surgery
  - Patient had therapeutic failure or intolerance to enoxaparin or Fragmin and fondaparinux
    OR
  - Patient has contraindication to enoxaparin, fondaparinux, and Fragmin (i.e., allergic to pork, history of heparin induced thrombocytopenia)

  - **6 months**

  **Upper extremity DVT**
  - **3 months**

  **Lower-limb SVT**
  - **45 days**

  **VTE treatment for warfarin failure or in cancer**
  - **6 months**

**Renewal:**

Length of renewal authorization based on anticipated length of therapy, indication and/or recent INR if on warfarin

**Initial Approval:**

- Osteoporosis – Indefinite
- Paget’s Disease: 1 time
### Insulin Pens

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Boniva</td>
<td>• Decrease in T-score in comparison with baseline T-score from DEXA scan OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• New fracture</td>
<td></td>
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<td></td>
<td>• Boniva only: must be female</td>
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</tbody>
</table>

**Treatment of corticosteroid-induced osteoporosis for those who meet the following criteria:**

*(Boniva, Reclast)*

- Treatment with 7.5 mg/day oral prednisone (or equivalent) for a planned duration of at least 3 months
- Baseline T-score < -1.0, with DEXA scan
- Failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate per medical records (for any length of time)

**For the treatment of Paget’s disease of bone in men and women who meet the following criteria:**

- Diagnosis of Paget’s disease
- Failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate per medical records (for any length of time)

### Initial Approval:

- Adults: Indefinite
- Children: through 18 years of age
### Interferons

#### α-Interferon

- **Infergen**
- **Intron A**
- **Pegasys**
- **Pegintron**
- **Sylatron**

#### β-Interferon

See Multiple Sclerosis Agents

#### γ-Interferon

- **Actimmune**

### Chronic Hepatitis B Infection:

*Intron A, Pegasys*

**Patients with HBeAg-positive or HBeAg-negative chronic hepatitis B**

- Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician
- HBeAg-positive or HBeAg-negative
- Compensated liver disease (e.g., normal bilirubin, albumin within normal limits, no cytopenias)
- Evidence of viral replication (e.g., HBV DNA > 20,000 IU/ml)
- Evidence of liver inflammation (e.g., ALT > 2 times the upper limit of normal, inflammation or fibrosis on liver biopsy)
- Age restriction *(Pegasys)*: Must be at least 18 years old
- Age restriction *(Intron A)*: Must be at least 1 year old

#### AIDS-related Kaposi's sarcoma:

*Intron A [powder for solution ONLY]*

- Prescribed by, or in consultation with an infectious disease physician or HIV specialist
- Not being used for the treatment of visceral AIDS-related Kaposi's sarcoma associated with rapidly progressive disease
- Patient must be at least 18 years old

#### Hairy-cell Leukemia:

*Intron A*

### Initial Approval:

- **Hepatitis B**
  - Intron A – 16 weeks
  - Pegasys – 48 weeks
- **Malignant Melanoma**
  - Intron A: 1 year
  - Sylatron: up to 5 years
- **Osteopetrosis, CGD**
  - 3 months
- **Kaposi's sarcoma**
  - 16 weeks
- **Hairy cell leukemia**
  - 6 months

### Duration of approval if requirements are met

- **Osteopetrosis, CGD**: 1 year
<table>
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<th>Duration of approval if requirements are met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hairy cell leukemia: 6 months</td>
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</tbody>
</table>

- Prescribed by, or in consultation with a hematologist/oncologist
- Patient has demonstrated less than complete response to cladribine or pentostatin OR
- Patient has relapsed within 1 year of demonstrating a complete response to cladribine or pentostatin
- Patient has indications for treatment such as:
  - Systemic symptoms – fatigue, weakness, weight loss, fever, night sweats
  - Symptomatic splenomegaly or adenopathy
  - Significant cytopenias – hemoglobin < 12 g/dL, platelet count < 100,000/mcL, or ANC < 1000/mcL
- Patient is at least 18 years old

**Malignant Melanoma:**  
*(Intron A, Sylatron)*

- Prescribed by, or in consultation with a hematologist/oncologist
- Patient has undergone surgical resection AND is at high risk for recurrence (e.g., primary tumor > 4 mm thick, presence of ulceration, lymph node involvement)
- Patient is at least 18 years old

**Chronic Granulomatous Disease:**  
*(Actimmune)*

- Prescribed by, or in consultation with an immunologist
- Patient is also receiving prophylactic antimicrobials (such as itraconazole and trimethoprim/sulfamethoxazole)

**Malignant Osteopetrosis:**  
*(Actimmune)*

- Prescribed for the treatment of severe, malignant osteopetrosis
# Intravaginal Progesterone Products (progesterone capsules, Crinone, First-progesterone suppositories)

For patients that meet the following:
- Prescribed by a provider of obstetrical care
- Patient is not on Makena (17-hydroxyprogesterone)
- Patient is pregnant and has 1 of the following:
  - Patient has a short cervix
  - OR
  - Patient is at high risk for pregnancy loss based on other risk factors

**Initial Approval:**
Approve as requested until 37 weeks gestation

---

## Guanfacine ER (Intuniv)/Clonidine ER (Kapvay)

Guanfacine ER (Intuniv) requires step therapy and is authorized for the treatment of attention-deficit hyperactivity disorder (ADHD) in members 6 years of age and older after trial and failure of clonidine or guanfacine in the past 6 months.

Authorization of clonidine ER (Kapvay) requires trial and failure of guanfacine ER (Intuniv)

**Indefinitely**

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## Lyrica (†)

Last reviewed: 10/21/2015

Lyrica is authorized for members who are 18 years of age or older with a diagnosis of post herpetic neuralgia or partial onset seizures.

**Criteria for the diagnosis of fibromyalgia:**
- Patient is 18 years of age or older
- Failure of a compliant 3-month trial of BOTH of the following:
  - Duloxetine at maximum tolerated doses
  - Gabapentin OR a tricyclic antidepressant (i.e., amitriptyline or nortriptyline) at maximum tolerated doses

**Criteria for the diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, spinal cord injury, or cancer-related neuropathic pain:**
- Patient is 18 years of age or older
- Trial and failure of a compliant 3-month trial of duloxetine AND at least 1 other generic formulary agent such as topical capsaicin, tricyclic antidepressants, tramadol, venlafaxine, or gabapentin at maximum tolerated doses

**Initial Approval:**
Indefinite
<table>
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</table>
| 17-hydroxyprogesterone        | covered for members who meet the following criteria:  
  - Covered for patients with a singleton pregnancy with a history of a spontaneous preterm singleton delivery, defined as delivery of an infant before 37 weeks gestation.  
  Patient must start injections between 16 weeks, 0 days and 20 weeks, 6 days gestation and discontinue after 36 weeks, 6 days gestation | Initial Approval:  
  - Until 37 weeks gestation |
| Multaq                        | Multaq will be authorized when prescribed by, or in consultation with a cardiologist. If not prescribed by or in consultation with a cardiologist, the following must be met:  
  - Diagnosis is atrial fibrillation  
  - Patient has tried and failed amiodarone  
  - Age restriction: must be at least 18 years old | Indefinitely |
| Neumega                      | May be authorized for the treatment of chemotherapy-induced thrombocytopenia when the following are met:  
  - Prescribed by a hematologist/oncologist  
  - Patient is at least 12 years old  
  - Patient has a non-myeloid malignancy and is receiving myelosuppressive chemotherapy  
  - Patient is at high risk of severe thrombocytopenia or has experienced severe thrombocytopenia with a previous chemotherapy cycle  
  - Administered 6 – 24 hours after the completion of chemotherapy  
  - NOT being used in the following situations:  
    o After myeloablative therapy  
    o Chemotherapy regimen longer than 5 days  
  Concurrently with agents associated with delayed myelosuppression (e.g., nitrosoureas, mitomycin C) | Initial Approval:  
  - Up to 21 days’ supply  
  - Refills if number of cycles provided  
  Renewal:  
  - Approval up to 1 year  
  Requires recent platelet count |
| Northera                      | For patients that meet all of the following:  
  - At least 18 years old  
  - Patient has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy  
  - Patient has tried and failed or has contraindication/intolerance to fludrocortisone and | Approval Initial:  
  - 6 months |
<table>
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<tr>
<th>Policy</th>
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<th>Duration of approval if requirements are met</th>
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<tbody>
<tr>
<td>Midodrine</td>
<td></td>
<td>Renewal: Indefinite</td>
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<tr>
<td><strong>Nucynta/ER</strong></td>
<td><strong>Nucynta immediate release:</strong></td>
<td>Initial Approval:</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of chronic pain</td>
<td>6 months</td>
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<td></td>
<td>• Patient is 18 years of age or older</td>
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<td></td>
<td>• Trial and failure of at least 2 formulary short-acting opioids such as:</td>
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<td>oxycodone, hydromorphone, morphine sulfate, oxycodone/apap</td>
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<td></td>
<td><strong>Nucynta ER for treatment of chronic pain:</strong></td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>• Patient must be at least 18 years of age or older AND</td>
<td>6 months</td>
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<td></td>
<td>• Trial and failure of maximum tolerated dose of two formulary long-acting</td>
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<td>agents (i.e., fentanyl patch, morphine sulfate ER, methadone) OR</td>
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<td></td>
<td>• Contraindication to formulary long-acting agents, AND</td>
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<td></td>
<td>• Trial and failure of Oxycontin, OR</td>
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<td></td>
<td>• Contraindication to Oxycontin</td>
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<td></td>
<td><strong>For diagnosis of diabetic peripheral neuropathy (Nucynta ER only):</strong></td>
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<td></td>
<td>• Patient must be at least 18 years of age or older AND</td>
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<td></td>
<td>• Must have diagnosis of diabetic peripheral neuropathy AND</td>
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<td></td>
<td>• Trial and failure of two formulary medications; such as, gabapentin, tricyclic antidepressants (amitriptyline, nortriptyline), tramadol, topical capsaicin AND</td>
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<tr>
<td></td>
<td>• Trial and failure of duloxetine or Lyrica</td>
<td></td>
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<tr>
<td><strong>Onychomycosis and Tinea</strong></td>
<td><strong>Luzu can be approved as non-formulary for members who meet the following:</strong></td>
<td>Initial (Luzu):</td>
</tr>
<tr>
<td></td>
<td>• Topical treatment of tinea pedis, tinea cruris, and tinea corporis.</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
<td>Renewal (Luzu):</td>
</tr>
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### AETNA BETTER HEALTH® OF NEW JERSEY

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<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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<tbody>
<tr>
<td>Luzu</td>
<td></td>
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<tr>
<td>Jublia</td>
<td></td>
<td></td>
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<tr>
<td>Kerydin</td>
<td></td>
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</table>

- Failure of OR contraindication to terbinafine cream
- Failure of at least 1 other formulary topical antifungal agents (ie clotrimazole, ciclopirox, econazole, ketoconazole, miconazole, etc.) OR contraindication to all formulary agents

Jublia or Kerydin can be approved as non-formulary for members who meet the following:

- Treatment of onychomycosis of the toenails with ONE of the following comorbidities:
  - Diabetes
  - HIV
  - Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications)
  - Peripheral vascular disease
  - Pain caused by the onychomycosis
- At least 18 years old

Failure of 2 OR contraindication to all formulary antifungal agents indicated for onychomycosis (ie ciclopirox, griseofulvin, itraconazole and terbinafine tablets)

- 30 days if responding to therapy

**Jublia or Kerydin:**
- 48 weeks

### Oral Anticoagulants

<table>
<thead>
<tr>
<th>Eliquis</th>
<th>Pradaxa</th>
<th>Xarelto</th>
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</thead>
</table>

Prescriptions for Eliquis, Xarelto and Pradaxa will automatically process for up to a 45 day duration to prevent delays in therapy. A PA will be required for prescriptions filled after the initial 45 days.

Eliquis, Xarelto and Pradaxa may be approved for patients who are at least 18 years old for the treatment of non-valvular atrial fibrillation, DVT, and PE. Patients do NOT need a trial of warfarin

**Duration of Approval:**

- Atrial fibrillation, Artificial Valves, post Cardiac Surgery and Prophylaxis for high risk conditions such as VTE.
  - Indefinite
- Tx of VTE (not prophy)
  - 6 months
# AETNA BETTER HEALTH® OF NEW JERSEY

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</table>
| **Oral Platelet Inhibitors**<sup>[ix]</sup>  
Last reviewed: 07/1/15  
Effient  
Brilinta  
Zontivity | Effient or Brilinta can be approved for patients who meet the following:  
- Diagnosis of ACS (unstable angina, STEMI, NSTEMI)  
- Failure or contraindication/intolerance to clopidogrel, including patients identified as CYP2C19 poor metabolizers  
- No active pathological bleeding, history of intracranial hemorrhage, or planned CABG  
- **In addition, for Effient:**  
  1. Age <75 unless patient is considered high thromboembolic risk  
  2. Taking concomitant 75-325mg/day aspirin  
  3. No history of TIA or stroke  
- **In addition, for Brilinta:**  
  1. Taking concomitant 75-100mg/day aspirin  
  2. No severe hepatic impairment  
  3. No concomitant use with medications known to interact with Brilinta (i.e., potent CYP3A4 inhibitors/inducers and simvastatin or lovastatin in doses >40mg/day) without provider documentation that benefit outweighs the risk  
- **Zontivity can be approved for patients who meet the following:**  
  - Prescribed for the secondary prevention of atherothrombosis in patients with PAD or history of MI (drug NOT indicated for ACS)  
  - Must be used with aspirin and/or clopidogrel according to the standard of care for the patient’s diagnosis  
  - No evidence of contraindications: history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH); or active pathological bleeding | **Initial Approval (Effient and Brilinta):**  
12 months  
Indefinite approval can be given to patients with a history of stent thrombosis/restenosis  
**Initial Approval (Zontivity):**  
Indefinite  
**Renewals (Effient and Brilinta):**  
12 months; requires documentation from cardiologist that risk of thrombosis outweighs bleeding risk with long-term use of antiplatelets |
| Orencia | **For patients who meet all of the following:**  
- Must be prescribed by, or in consultation with a rheumatologist  
- May not be given in combination with TNF-alpha antagonists (e.g. Enbrel, Humira, or Remicade) | **Indefinitely** |

## Treatment of Rheumatoid Arthritis for patients 18 years of age and older (IV infusion or SC injection):
## Policy Requirements

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
</tr>
</thead>
</table>
| • Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs) **AND**
  • Trial and failure of, or contraindication/intolerance to at least 3 months compliant regimen of Enbrel or Humira |                                            |

### Treatment of Juvenile Idiopathic Arthritis for 6 years of age and older (IV infusion only):
- After trial and failure of a compliant regimen of methotrexate for at least 3 months, **AND**
- Trial and failure of, or contraindication/intolerance to at least 3 months of a compliant regimen of Enbrel or Humira

### Long Acting Opioids

Last reviewed: 5/13/15

<table>
<thead>
<tr>
<th>Oxycontin</th>
<th>Butrans Patch</th>
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<tbody>
<tr>
<td>Exalgo</td>
<td>Oxymorphone ER</td>
</tr>
<tr>
<td>Zohydro ER</td>
<td>Xartemis XR</td>
</tr>
<tr>
<td>Nucynta ER</td>
<td>Morphine Sulfate ER</td>
</tr>
<tr>
<td>Fentanyl Patch</td>
<td>Methadone</td>
</tr>
</tbody>
</table>

### Criteria for ALL long-acting opioids (formulary and non-formulary):
- Patient has a treatment plan that includes the diagnosis and goals of therapy
- Prescriber has completed an addiction risk assessment for the specific therapy
- Prescriber has recently reviewed the state Prescription Monitoring Program (PMP) database
- Patient has a pain management contract that addresses the following:
  - Consequences of unexplained loss or shortage of medications
  - Consequences of obtaining similar prescription medications from other prescribers
  - An agreement with the member to only use one pharmacy

### In Addition, STEP criteria for Oxymorphone ER:
- Treatment of chronic pain
- At least 18 years old
- Failed a minimum of 2 week trials of maximum tolerated doses of at least TWO formulary long-acting opioids (i.e., fentanyl patch, morphine sulfate ER, methadone) OR have contraindications to all formulary agents.

### In Addition, Criteria for Oxycontin and Non-Formulary Long-Acting Opioids:
- Treatment of malignant pain and pain due to sickle cell anemia (Oxycontin)
- Treatment of chronic non-malignant pain:

### Initial Approval:
- 1 year

### Renewal:
- 1 year

NOTE: QL’s may exist
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<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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</thead>
</table>
|                            | o At least 18 years old  
  o Failed a minimum of 2 week trials of maximum tolerated doses of at least THREE formulary long-acting agents (i.e., fentanyl patch, morphine sulfate ER, methadone, oxymorphone ER) one of which must be oxymorphone ER  
  OR  
  o Contraindication to all formulary long-acting agents  
  OR  
  • Treatment of diabetic peripheral neuropathy (Nucynta ER only):  
    o At least 18 years old  
    o Failed an adequate trial (at least 4 weeks at maximum tolerated doses) of duloxetine and tramadol and at least ONE additional formulary medication (i.e., gabapentin, amitriptyline, nortriptyline, or topical capsaicin)  
    OR  
    o Contraindications to all formulary agents                                                                                                                                                                                                                                      |                                             |
| Omega-3 Carboxylic Acids*  | For patients that meet the following:  
  • At least 18 years old  
  • On an appropriate lipid-lowering diet and exercise regimen  
  • Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL)  
  Trial and failure of OTC fish oil and at least ONE other formulary medication such as fenofibrate, fenofibric acid, gemfibrozil, or OTC niacin or contraindication to all formulary agents                                                                                                                                                   | Initial Approval: Indefinite |
| Epanova                    |                                                                                                                                                                                                                                                                                                                                              |                                             |
| Otezla*                    | For moderate to severe psoriatic arthritis:  
  • Age is 18 years or older  
  • Prescribed by or in consultation with a rheumatologist  
  • Trial and failure of methotrexate for three consecutive months (or documentation showing contraindication)  
  • Trial and failure of Humira or Enbrel for three consecutive months (or documentation showing contraindication, non-responsiveness or diminished response over time)                                                                                                                                 | Initial Approval: 3 months  
  Renewal: 12 months |
### Policy Requirements

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<tbody>
<tr>
<td><strong>AETNA BETTER HEALTH® OF NEW JERSEY</strong></td>
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<tr>
<td><strong>Policy</strong></td>
<td><strong>Requirements</strong></td>
<td></td>
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<tr>
<td>For moderate to severe plaque psoriasis:</td>
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<td></td>
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<tr>
<td>• Age is 18 years or older</td>
<td></td>
<td>Requires:</td>
</tr>
<tr>
<td>• Prescribed by or in consultation with a dermatologist</td>
<td></td>
<td>• Patient experiencing positive response to therapy.</td>
</tr>
<tr>
<td>• Trial and failure of UVB or PUVA therapy or documentation showing contraindication</td>
<td></td>
<td>• Patient is not experiencing depression and/or suicidal thoughts.</td>
</tr>
<tr>
<td>• Trial and failure of methotrexate for three consecutive months (or documentation showing contraindication)</td>
<td></td>
<td>Patient has no significant weight loss.</td>
</tr>
<tr>
<td>• Trial and failure of Humira or Enbrel for three consecutive months (or documentation showing contraindication, non-responsiveness or diminished response over time)</td>
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<tr>
<td><strong>Non-Calcium Based Phosphate Binders</strong>&lt;sup&gt;iii&lt;/sup&gt;</td>
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<td></td>
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<tr>
<td>Last reviewed: 4/22/15</td>
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<tr>
<td>Fosrenol</td>
<td>For patients that meet all of the following:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Velphoro</td>
<td>• Treatment of hyperphosphatemia due to ESRD</td>
<td>Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Receiving dialysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At least 18 years old</td>
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<tr>
<td>Failed Renvela or Renagel (sevelamer) AND failed a calcium-based phosphate binder or has contraindications to both. (Note: Patients with elevated total serum calcium after correcting for albumin should not receive a calcium-based product)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Promacta</strong>&lt;sup&gt;iii&lt;/sup&gt;</td>
<td>Chronic idiopathic thrombocytopenic purpura (ITP):</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Last reviewed: 4/22/15</td>
<td>• Patient is at least 18 years old</td>
<td>1 month</td>
</tr>
<tr>
<td></td>
<td>• Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy</td>
<td>Renewal:</td>
</tr>
<tr>
<td></td>
<td>• Promacta is being used to prevent major bleeding (not in an attempt to achieve platelet counts in the normal range i.e., 150,000-450,000/mm³)</td>
<td>ITP and aplastic anemia: Indefinite</td>
</tr>
<tr>
<td></td>
<td><strong>Interferon-induced thrombocytopenia:</strong></td>
<td></td>
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<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td></td>
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<tr>
<td></td>
<td>• Patient has chronic hepatitis C with severe thrombocytopenia which prevents initiation or ability to maintain interferon-based therapy</td>
<td>HCV: 1 year</td>
</tr>
<tr>
<td></td>
<td><strong>Severe aplastic anemia</strong></td>
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</tr>
<tr>
<td></td>
<td>• Patient is at least 18 years old</td>
<td></td>
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<tr>
<td>Policy</td>
<td>Requirements</td>
<td>Duration of approval if requirements are met</td>
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</table>
|        | • Patient has a diagnosis of severe aplastic anemia defined by at least 2 of the following:  
  o Neutrophil count < 0.5 x 10⁹/L  
  o Platelet count < 20 x 10⁹/L  
  o Reticulocyte count < 20 x 10⁹/L (value may be given as percent of RBCs)  
Trial of or contraindication to first line treatment including allogeneic stem cell transplantation from an appropriate sibling donor or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG) | Renewal requirements:  
• Platelet count of at least 50,000/mm³ (response rates should be seen at least 1 week after initiation of therapy with a maximum response seen at 2 weeks)  
Severe aplastic anemia response to treatment would be indicated by hematologic response in at least one lineage – platelets, RBC or WBC. |
### Proton Pump Inhibitors

- Prilosec OTC, Nexium OTC, and Prevacid OTC are the formulary preferred agents.
- Non-preferred PPI’s can be authorized when the following criteria are met:
  - Trial and failure of at least TWO formulary PPI’s
  - Trial and failure of at least ONE formulary PPI at double-daily dose:
    - Prilosec OTC 40mg
    - Nexium OTC 40mg
    - Prevacid OTC 60mg
- High Dose PPI’s can be authorized when the following criteria are met:
  - Provider must submit rationale for high dose (e.g., patient has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison)
  - Patient must have failed Prilosec OTC 40mg, Nexium OTC 40mg, and Prevacid OTC 60mg

<table>
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<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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</thead>
</table>
| Proton Pump Inhibitors | Prilosec OTC, Nexium OTC, and Prevacid OTC are the formulary preferred agents. Non-preferred PPI’s can be authorized when the following criteria are met:  
  - Trial and failure of at least TWO formulary PPI’s  
  - Trial and failure of at least ONE formulary PPI at double-daily dose:  
    - Prilosec OTC 40mg  
    - Nexium OTC 40mg  
    - Prevacid OTC 60mg  
  High Dose PPI’s can be authorized when the following criteria are met:  
  - Provider must submit rationale for high dose (e.g., patient has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison)  
  - Patient must have failed Prilosec OTC 40mg, Nexium OTC 40mg, and Prevacid OTC 60mg | Initial Approval: Once daily NF: Indefinite  
Renewal: High dose: 12 months  
Requires: Response to therapy and rationale for continuing BID dosing |

| Pulmonary Arterial Hypertension (PAH) | All agents must be prescribed by, or in consultation with a pulmonologist or cardiologist with experience in treating Pulmonary Hypertension.  
  - Age restriction (Revatio): must be at least 17 years old  
  Additional information may be required on a case-by-case basis to allow for adequate review and to ensure the safety of the patient. | Indefinitely |
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<tbody>
<tr>
<td>Ventavis, Tyvaso</td>
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</table>
| Modafinil/Nuvigil[^vi] | • Modafanil is the preferred formulary agent, however still requires PA. Nuvigil is non-formulary and may be authorized if the patient meets criteria and also has a documented trial and failure of modafanil. | Initial Approval:  
- 6 months  
Renewal:  
- 1 year  
Requires a response to treatment  
For OSA: patient must be compliant with CPAP or BIPAP  
For SWD: patient must still be a shift-worker |
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</table>
|        | • May be authorized for patients at least 17 years old for the treatment of excessive sleepiness associated with idiopathic hypersomnia when the following criteria is met:  
  • Prescribed by, or in consultation with, a sleep specialist  
  • Trial and failure of 2 formulary stimulants (e.g., amphetamine/dextroamphetamine, methylphenidate)  
  • Diagnosis is supported by polysomnography, MSLT, and clinical evaluation including the following:  
    • Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months  
    • MSLT documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤15 minutes  
    • The presence of at least one of the following:  
      • MSLT shows a mean sleep latency of ≤8 minutes  
      • Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log  
      • Other causes of sleep disorder have been ruled out  
    • The sleepiness is significantly impacting, impairing, or compromising the patient’s ability to function normally  | 4 months |
| Orencia | General authorization criteria for all indications:  
  • Prescribed by a rheumatologist  
  • Patient is NOT on another biological DMARD  
  • Patient is up to date with all recommended vaccinations  
  • Patient has been screened for latent TB and hepatitis B | 4 months  
  Renewals:  
  • Indefinite  
Renewals require at least 20% symptom improvement |
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<td>• Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:</td>
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<td>o 2 different oral DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)</td>
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<tr>
<td></td>
<td>▪ Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)</td>
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<td></td>
<td>▪ Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ</td>
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<tr>
<td></td>
<td>o ONE formulary anti-TNF (Note: anti-TNF’s require PA)</td>
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<tr>
<td>In addition, May be authorized for Juvenile Idiopathic Arthritis (JIA) when the following are met:</td>
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<tr>
<td></td>
<td>• Patient is at least 6 years old</td>
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<td></td>
<td>• Request is for the IV formulation</td>
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<td></td>
<td>• For SEVERE Polyarticular JIA:</td>
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<tr>
<td></td>
<td>o Patient has failed an adequate 3-month trial with ONE formulary anti-TNF</td>
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<td></td>
<td>• For MODERATE Polyarticular JIA:</td>
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<td></td>
<td>o Patient has failed an adequate 3-month trial of MTX AND one formulary anti-TNF</td>
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<td>• For Systemic JIA:</td>
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<td></td>
<td>o Patient does NOT have currently ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)</td>
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<tr>
<td></td>
<td>o Patient has continued synovitis in ≥1 joint despite treatment for 3 months with MTX or leflunomide AND one formulary anti-TNF</td>
<td></td>
</tr>
<tr>
<td><strong>Platelet Inhibitors</strong></td>
<td><strong>For patients that meet the following:</strong></td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Effient</td>
<td>• Diagnosis of acute coronary syndrome (e.g., unstable angina, STEMI, NSTEMI)</td>
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<tr>
<td>Brilinta</td>
<td>• Failure or contraindication/intolerance to clopidogrel</td>
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<tr>
<td></td>
<td>• Age restriction: must be at least 18 years old</td>
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<td></td>
<td><strong>For patients age 18 years of age or older who meet all of the following:</strong></td>
<td>Initial Approval: Indefinite</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of chronic angina</td>
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<td></td>
<td>• Patient meets ONE of the following:</td>
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<tr>
<td></td>
<td>• Ranexa is prescribed as ADD-on therapy after failure to achieve therapeutic benefit on at least 1 such therapeutic agent for the treatment of chronic angina for the duration of the treatment.</td>
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<td>formulary agent from EACH of the following 3 drug classes:</td>
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<tr>
<td></td>
<td>▪ <strong>Beta blockers</strong>: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol</td>
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<tr>
<td></td>
<td>▪ <strong>Calcium channel blockers</strong>: amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil</td>
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</tr>
<tr>
<td></td>
<td>▪ <strong>Long acting nitrates</strong>: Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch</td>
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<tr>
<td></td>
<td>Has a documented contraindication or intolerance to beta blockers, calcium channel blockers, AND long-acting nitrates</td>
<td></td>
</tr>
<tr>
<td>Remicade</td>
<td>For patients who meet all of the following:</td>
<td>Initial Approval:</td>
</tr>
<tr>
<td>Remicade</td>
<td>• Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist)</td>
<td>6 months</td>
</tr>
<tr>
<td>Remicade</td>
<td>• Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret</td>
<td>Renewal:</td>
</tr>
<tr>
<td>Remicade</td>
<td>For treatment of ankylosing spondylitis, all of the following:</td>
<td>1 year with documentation to support a response to treatment</td>
</tr>
<tr>
<td>Remicade</td>
<td>• 18 years of age, or older, and</td>
<td></td>
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<tr>
<td>Remicade</td>
<td>• Trial and failure of a compliant regimen of two formulary NSAIDs within the last 60 days (or documented contraindication or intolerance to NSAIDs); and</td>
<td></td>
</tr>
<tr>
<td>Remicade</td>
<td>• Trial and failure of a compliant regimen of Enbrel or Humira for three consecutive months (or documented contraindication or intolerance to Enbrel and Humira)</td>
<td></td>
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</table>
For treatment of fistulizing Crohn’s Disease
- 18 years of age, or older
- Diagnosis of fistulizing Crohn’s Disease

For treatment of chronic severe plaque psoriasis, all of the following:
- 18 years of age, or older,
- Trial and failure of UVB or PUVA therapy or documentation showing contraindication to therapy,
- Trial and failure of a compliant regimen of methotrexate for three consecutive months (or documentation showing contraindication to methotrexate); and
- Trial and failure of a compliant regimen of Enbrel or Humira for three consecutive months (or documented contraindication or intolerance to Enbrel and Humira)

For treatment of moderate to severe psoriatic arthritis, all of the following:
- 18 years of age, or older,
- Trial and failure of a compliant regimen of methotrexate for at least three months (or documented contraindication or intolerance to methotrexate), and
- Trial and failure of a compliant regimen of Enbrel or Humira for three months (or documented contraindication or intolerance to Enbrel and Humira)

For treatment of moderate to severe RA:
- 18 years of age, or older, and
- Will be used with methotrexate, and
- One of the following:
# AETNA BETTER HEALTH® OF NEW JERSEY

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Trial and failure of a compliant regimen of methotrexate in combination with sulfasalazine, hydroxychloroquine or leflunomide for at least 3 months,</td>
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<tr>
<td></td>
<td>Trial and failure of monotherapy with methotrexate for at least 3 months and trial and failure of monotherapy with sulfasalazine, hydroxychloroquine or leflunomide for at least 3 months, or</td>
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<td></td>
<td>Documented contraindication or intolerance to methotrexate and other DMARDs</td>
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<td></td>
<td>● And, trial and failure of a compliant regimen of Enbrel or Humira for three months (or documented contraindication or intolerance to Enbrel and Humira)</td>
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</tbody>
</table>

For treatment of moderate to severe active ulcerative colitis, all of the following:

- 6 years of age, or older,
- Trial and failure of a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months (or documented contraindication or intolerance to aminosalicylates);
- Trial and failure of a compliant regimen of oral or intravenous corticosteroids for one month (or documented contraindication or intolerance to PO or IV corticosteroids);
- Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months (or documented contraindication or intolerance to azathioprine or mercaptopurine
- Trial and failure of a compliant regimen of Humira for at least two months (Adults)

<table>
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<tr>
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<tbody>
<tr>
<td>Octreotide</td>
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<tr>
<td>Sandostatin LAR</td>
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<td>Signifor, Signifor LAR</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Stelara</th>
<th>For the treatment of chronic moderate to severe plaque psoriasis:</th>
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<tbody>
<tr>
<td></td>
<td>● Patient is a candidate for phototherapy or systemic therapy</td>
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<td></td>
<td>● Patient is 18 years old or older</td>
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<tr>
<td></td>
<td>● Failure of or contraindication/intolerance to a 3-month trial of phototherapy (i.e., PUVA, UVB)</td>
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<tr>
<td></td>
<td>● Failure of or contraindication to a 3-month trial of Enbrel and Humira</td>
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Indefinitely
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<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
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</thead>
<tbody>
<tr>
<td>For the treatment of active psoriatic arthritis:</td>
<td>• Failure of or contraindication/intolerance to intolerance to a 3-month trial of Enbrel and Humira • Patient is 18 years old or older</td>
<td></td>
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<tr>
<td>Symlin</td>
<td>For patients that meet all of the following:</td>
<td>Indefinitely</td>
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<tr>
<td></td>
<td>• Diagnosis of Type 1 or Type 2 DM • Prescribed by, or in consultation with an endocrinologist • Patient is 18 years of age or older • Patient is currently on mealtime bolus insulin (e.g., Novolog, Humalog) • Patient failed to achieve desired glucose control with optimal insulin therapy • Patient does not have any of the following: o Hypoglycemia unawareness or recurrent episodes of hypoglycemia o Gastroparesis o Poorly controlled diabetes (e.g., A1c &gt; 9%) o Poor adherence to current insulin regimen</td>
<td></td>
</tr>
<tr>
<td>Synagis</td>
<td>For patients in one of the following groups:</td>
<td>Initial Approval 1 dose per month for a maximum of 5 doses per season <strong>Note: infants born during RSV season may require fewer than 5 doses</strong></td>
</tr>
<tr>
<td>A. Preterm Infants without Chronic Lung Disease (CLD):</td>
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<tr>
<td></td>
<td>• Gestational Age (GA) &lt; 29 weeks, 0 days AND • 12 months of age or younger at the start of RSV season</td>
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<tr>
<td>B. Preterm Infants with Chronic Lung Disease (CLD):</td>
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<td></td>
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<tr>
<td></td>
<td>• Gestational Age (GA) &lt; 32 weeks, 0 days AND • Has required &gt; 21% oxygen for at least 28 days after birth AND • 12 months of age or younger at the start of RSV season OR • 24 months of age at the start of RSV season AND continues to require medical support (e.g., supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of RSV season</td>
<td></td>
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</tbody>
</table>
AETNA BETTER HEALTH® OF NEW JERSEY

| Policy                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                    | Duration of approval if requirements are met |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| C. Infants with Hemodynamically Significant Congenital Heart Disease: | - 24 months of age or younger AND has undergone cardiac transplantation during RSV season OR  
  - 12 months of age or younger at the start of RSV season AND  
  - Meets one of the following:  
    o Diagnosis of acyanotic heart disease  
      ▪ Must be currently receiving medication to control congestive heart failure  
      ▪ Will require cardiac surgical procedure  
    o Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist  
    o Diagnosis of moderate to severe pulmonary hypertension |                                                                                     |
| D. Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder: | - 12 months of age or younger AND  
  - Diagnosis of neuromuscular disease or congenital anomaly that impairs ability to clear secretions from the upper airway because of ineffective cough |                                                                                     |
| E. Immunocompromised Children: | - 24 months of age or younger at the start of RSV season AND  
  - Child is profoundly immunocompromised during RSV season |                                                                                     |

**Note:** The following groups are not at increased risk of RSV and should NOT receive Synagis:

1. Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
2. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
### Policy Requirements

<table>
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<tr>
<th>Policy</th>
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<th>Duration of approval if requirements are met</th>
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<tbody>
<tr>
<td>3. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition</td>
<td></td>
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<tr>
<td>Children with cystic fibrosis (unless the child has clinical evidence of CLD and/or nutritional compromise in the first year of life) or Down Syndrome (unless qualifying heart disease or prematurity)</td>
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</tbody>
</table>

### Therapeutic Duplication

**Prior authorization is required when multiple medications within the same drug class are taken concomitantly and applies to the following list of drugs/drug classes:**

- ACE Inhibitors & Angiotensin Receptor Blockers
- Antidepressants, SSRI & SNRI
- Antihistamines, 1\(^{st}\) and 2\(^{nd}\) generation
- Atypical antipsychotics
- Bladder antispasmodics
- HIV (NNRTI, NRTI, Protease Inhibitors)
- Hypnotics
- Inhaled corticosteroids
- LABAs
- NSAIDs/COX-II
- Long acting opiates
- Short acting opiates
- Proton Pump Inhibitors
- Skeletal muscle relaxants
- Statins
- Stimulants, long and short-acting
- Triptans

**Approved for patients who meet the following:**

- Being titrated to, or tapered from a duplicate agent **OR**
- Documentation of peer reviewed literature or national treatment guidelines to support concurrent use of the duplicate medications **AND**

**Initial Approval:**

One time override or as medically necessary up to one year.
### Policy Requirements

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<thead>
<tr>
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<th>Duration of approval if requirements are met</th>
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</thead>
</table>
|                                | • Does not exceed established quantity limits  
AND For atypical antipsychotic duplication:  
• Both atypical antipsychotics involved in the therapeutic duplication are prescribed by the same psychiatrist AND  
• Antipsychotic is NOT added as a first-line intervention for insomnia in adults or NOT the first augmentation strategy for depression AND  
• Member failed an adequate trial and dose of single antipsychotic agent |                                                            |
| Topical Calcineurin Inhibitors\(\textsuperscript{[i]}\) | Elidel and tacrolimus are covered for patients between 2 and 10 years of age.  
For other age groups, Elidel and tacrolimus require step therapy with topical corticosteroids.  
• If patient has filled 2 topical corticosteroids in the last 60 days, the prescription will automatically process at the pharmacy.  
• Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, Elidel and tacrolimus will be reviewed for the treatment of eczema or atopic dermatitis based upon the affected area being treated:  
  o Body/extremities – authorized after trial and failure or intolerance to at least 2 different formulary topical corticosteroids.  
  o Face – authorized after trial and failure of one formulary low-potency topical corticosteroid  
  o Eyelid or other sensitive area – authorized without trial and failure of topical corticosteroids | Initial Approval:  
Indefinite |
| Elidel Tacrolimus              |                                                                                                                                             |                                                            |
| Topical NSAIDs\(\textsuperscript{[x]}\) (Aetna Version) | Criteria for Approval:  
A. Age 18 or older  
B. History of or high risk for adverse GI effects associated with oral NSAID use AND trial and failure of celecoxib;  
OR  
C. High risk for other adverse effects associated with oral NSAID use (i.e., CHF, renal failure, concomitant use of lithium); OR  
D. Failure on TWO formulary NSAIDs  
E. Diagnosis of OA of knee or hand for Voltaren gel  
F. Diagnosis of OA of knee for Pennsaid  

Note: Flector patch is only FDA approved for acute pain. Requests for Flector patch for chronic pain should be | Initial Approval:  
Flector Patch: 1 month  
All others: 1 year  
Renewal:  
Flector Patch: 1 month  
All others: 1 year |
### Tranexamic acid tablets

**Criteria for the treatment of cyclic heavy menstrual bleeding:**
- Diagnosis of cyclic heavy menstrual bleeding (menstrual blood loss of > 80mL per menstrual cycle)
- Trial and failure, intolerance or contraindication to oral NSAIDs
- Trial and failure, intolerance or contraindication to oral combination contraceptives, oral progesterone, Mirena, or Depo Provera
- Age restriction: 12 years of age or older

Tranexamic acid may also be authorized for the treatment of acute bleeding episodes in patients with hemophilia.

<table>
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<tr>
<th>Policy</th>
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</thead>
</table>
| Tranexamic acid tablets | denied. If patient meets all other criteria above, offer Voltaren Gel or Pennsaid as an alternative. The risk factors that correlate strongly to adverse GI effects of oral NSAID use are:  - History of GERD, GI bleed, or ulcer  - Chronic oral steroid use  - Current anticoagulant or antiplatelet use  - Age 65 or greater | Initial Approval:  
90 days for menstrual bleeding  
Indefinite for hemophilia  
Maximum of 30 tablets per 30 days for menstrual bleeding.  
Maximum of 84 tablets per 30 days for hemophilia |

### Trospium, trospium ER (Sanctura/XR)

Trospium and trospium XR require step therapy with oxybutynin/oxybutynin ER for the treatment of overactive bladder. If member has filled oxybutynin/oxybutynin ER within the last 130 days, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, trospium or trospium XR will be authorized upon receipt of documentation to support member is at least 18 years old, and failure of, or contraindication to oxybutynin/oxybutynin ER.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trospium, trospium ER (Sanctura/XR)</td>
<td></td>
<td>Indefinitely</td>
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</table>

### Second Generation Tyrosine Kinase Inhibitors for CML and ALL [vi]

Gleevec (a first generation TKI) is the preferred agent for CML and ALL (see Gleevec guideline for PA coverage criteria). Gleevec should NOT be used in patients who have had a treatment failure with a second generation TKI. Tasigna is the formulary preferred second generation TKI and is subject to the PA criteria included below.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
</tr>
</thead>
</table>
| Second Generation Tyrosine Kinase Inhibitors for CML and ALL [vi] | | Initial: 1 year  
Renewal: 3 years approved as long as there is no evidence of disease |
**AETNA BETTER HEALTH® OF NEW JERSEY**

<table>
<thead>
<tr>
<th>Policy</th>
<th>Requirements</th>
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</thead>
<tbody>
<tr>
<td>Tysabri</td>
<td>For patients who meet all of the following:</td>
</tr>
<tr>
<td></td>
<td>• Must be prescribed by a neurologist or gastroenterologist, based on indication</td>
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<tr>
<td></td>
<td>• Must be prescribed for an FDA approved indication</td>
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<tr>
<td></td>
<td>• Must be 18 years of age or older</td>
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<td></td>
<td>• Not taking antineoplastic, immunosuppressive, or immunomodulating agents (e.g., azathioprine, 6-</td>
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<tr>
<td></td>
<td><strong>Initial Approval:</strong></td>
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<tr>
<td></td>
<td>Approve for 3 months</td>
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<tr>
<td></td>
<td><strong>Renewal:</strong></td>
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<tr>
<td></td>
<td>For Crohn’s Disease:</td>
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<thead>
<tr>
<th>Status</th>
<th>Requirements</th>
<th>Duration of approval if requirements are met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last reviewed: 10/30/2015</td>
<td>Second Generation TKI’s when prescribed for adult patients (at least 18 years of age) by an oncologist may be authorized when the following criteria are met:</td>
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<tr>
<td></td>
<td>• Patient has ONE of the following diagnoses:</td>
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<tr>
<td></td>
<td>o Philadelphia chromosome positive or BCR-ABL1 positive chronic myeloid leukemia (Ph+ CML) in chronic phase or accelerated phase</td>
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<tr>
<td></td>
<td>o Relapsed, refractory Ph+ CML in blast phase when it is of lymphoid type (not myeloid)</td>
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<td></td>
<td>o Relapsed, refractory Ph+ acute lymphoblastic leukemia (Ph+ ALL)</td>
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<td></td>
<td>o NOTE: The efficacy of TKI’s has not been evaluated in clinical trials for the treatment of acute myeloid leukemia (AML)</td>
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<td></td>
<td>• In addition for Tasigna (formulary with PA) patient has ONE of the following:</td>
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<td></td>
<td>o Intolerance, disease progression, or resistance to prior therapy with Gleevec</td>
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<tr>
<td></td>
<td>o Intolerance, disease progression, or resistance to prior therapy with a second generation TKI (Sprycel, Bosulif, or Iclusig)</td>
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<tr>
<td></td>
<td>o Presence of any of the following mutations that are resistant to Gleevec: F317L/V/I/C, T315A, V299L</td>
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<td></td>
<td>• In addition for Sprycel or Bosulif (non-formulary) patient has ONE of the following:</td>
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<tr>
<td></td>
<td>o Intolerance, disease progression, or resistance to prior therapy with Gleevec AND Tasigna</td>
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<tr>
<td></td>
<td>o Intolerance, disease progression, or resistance to prior therapy with a second generation TKI (Tasigna, Bosulif, Sprycel or Iclusig)</td>
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<tr>
<td></td>
<td>o Presence of any of the following mutations that are resistant to Gleevec and Tasigna: Y253H, E255K/V, F359V/C/I</td>
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<td></td>
<td>• In addition for Iclusig (non-formulary) patient has ONE of the following:</td>
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<tr>
<td></td>
<td>o Intolerance, disease progression, or resistance to prior therapy with all other TKI’s (Gleevec, Tasigna, Sprycel, and Bosulif)</td>
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<td></td>
<td>o Presence of the T315I mutation that is resistant to other TKI’s</td>
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<td><strong>Renewals should be based on documentation of major cytogenetic response (≤35% Ph+ metaphases) and until disease progression or death</strong></td>
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**For Crohn’s Disease:**

- **Initial Approval:** Approve for 3 months
- **Renewal:** For Crohn’s Disease:
# AETNA BETTER HEALTH® OF NEW JERSEY

## Policy

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<tr>
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<tr>
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<td>mercaptopurine, cyclosporine, methotrexate, TNF-inhibitors)</td>
<td>• If patient has experienced therapeutic benefit, approve for 3 months</td>
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<td></td>
<td>• Will be used as monotherapy</td>
<td><strong>Additional Renewals:</strong></td>
</tr>
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<td></td>
<td><strong>For Crohn’s Disease:</strong></td>
<td></td>
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<tr>
<td></td>
<td>• Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) or intravenous corticosteroids (for severe and fulminant CD) for one month (or documented contraindication or intolerance to PO or IV corticosteroids); <strong>AND</strong></td>
<td></td>
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<tr>
<td></td>
<td>• Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months (or documented contraindication or intolerance to azathioprine or mercaptopurine); <strong>AND</strong></td>
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<td></td>
<td>• Trial and failure of a compliant regimen of Humira or Remicade for at least 3 months</td>
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<td>90 days</td>
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<td><strong>For Vivitrol:</strong></td>
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<td></td>
<td>• Must be at least 18 years of age</td>
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<td>• Not experiencing acute opiate agonist withdrawal</td>
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<td>• Not receiving opioid analgesics (e.g.; must pass naloxone challenge test or negative urine drug screen for opiates)</td>
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<td></td>
<td>• Must be enrolled in and compliant with a substance abuse treatment program or psychosocial support plan</td>
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<td></td>
<td>• Must be and remain abstinent from using all substances of abuse (as verified by random urine drug testing)</td>
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<tr>
<td></td>
<td>• For Alcohol dependence:</td>
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<td></td>
<td>➢ Abstinent from alcohol for at least 7 days in an ambulatory setting prior to the initiation of treatment</td>
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<td></td>
<td>➢ If also opioid-dependent, must be opioid-free for a minimum of 7-10 days before starting treatment in order to prevent unintentional withdrawal.</td>
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</table>
### AETNA BETTER HEALTH® OF NEW JERSEY

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</table>
| **Weight Reduction** | **For Patients who meet all of the following:** | **Initial Approval:** 3 months  
**Renewal:**  
- Orlistat (Xenical) and Belviq only: 3 months with documentation of a weight loss of at least 4 pounds per month  
- For all other weight loss medications: Treatment beyond 3 months is not recommended and is considered “off label”  
**Additional Renewal:**  
- Orlistat (Xenical) and Belviq only: 6 months to 1 year (no more than 4 years)  
Documentation to support member continues weight loss plan and has maintained 67% of their initial weight loss to date or continues weight loss |
| Medications |  
Xenical, Belviq, phentermine, Bontril, Didrex, Tenuate, Qsymia, Contrave |  
- BMI >= 30 kg/m² (obese) OR  
- BMI greater than or equal to 27kg/m² (overweight) and one of the following obesity-related risk factor  
  - Coronary heart disease  
  - Dyslipidemia:  
    - HDL <35mg/dl or  
    - LDL ≥ 160mg/dL, or  
    - Triglycerides ≥ 400mg/dl  
  - Controlled hypertension (less than 140/90mm Hg)  
  - Type II diabetes mellitus  
  - Sleep apnea  
  - Polycystic ovary syndrome  
  - OA  
- For Xenical: no contraindications such as chronic malabsorption syndrome, cholestasis, hepatic disease, hypersensitivity to orlistat, pregnancy  
- For Belviq: no contraindications such as pregnancy, concurrent use with (SSRIs), (SNRIs), (MAOIs), triptans, bupropion, dextromethorphan, St. John’s wort  
- For Contrave: member has been abstinent from opioids for a minimum of 7 – 10 days (up to 14 days if taking long-acting opioid) prior to starting naltrexone/bupropion, including treatment of alcohol dependence.  
- All others: no contraindications such as uncontrolled cardiovascular disease (cardiac arrhythmias, stroke, TIA, CHF, advanced artherosclerosis), uncontrolled hypertension |  
- For Opioid dependence:  
  - Opioid-free for a minimum of 7-10 days prior to the initiation of treatment in order to prevent unintentional withdrawal  
  - Documentation supports trial and failure of, intolerance to, or non-compliance with oral naltrexone and/or oral buprenorphine with or without naloxone (Subutex or Suboxone), or a rationale is provided to support the necessity of Vivitrol injections. |  
- Orlistat (Xenical) and Belviq only: 3 months  
- For all other weight loss medications: Treatment beyond 3 months is not recommended and is considered “off label”  
- Orlistat (Xenical) and Belviq only: 6 months to 1 year (no more than 4 years)  
Documentation to support member continues weight loss plan and has maintained 67% of their initial weight loss to date or continues weight loss |
### Xeljanz®

Last reviewed: 10/22/2015

May be authorized for Rheumatoid Arthritis (RA) when the following are met:

- Patient is at least 18 years old
- Prescribed by a rheumatologist
- Patient is NOT on a biological DMARD or azathioprine or cyclosporine
- Patient is up to date with all recommended vaccinations
- Patient has been screened for latent TB and hepatitis B
- Patient has moderate or high disease activity despite an adequate 3-month trial of BOTH of the following:
  - 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)
    - Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)
    - Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ
  - ONE formulary anti-TNF (Note: anti-TNF’s require PA)

<table>
<thead>
<tr>
<th>Duration of approval if requirements are met</th>
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<tbody>
<tr>
<td>Initial Approval: 3 months</td>
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<tr>
<td>Renewal: Indefinite</td>
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<tr>
<td>Renewals require at least 20% symptom improvement</td>
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</tbody>
</table>

### Xolair®

Last reviewed: 07/01/15

For the treatment of moderate-severe persistent asthma:

- Prescribed by, or after consultation with a pulmonologist or allergist/immunologist
- 12 years of age or older
- Baseline IgE levels between 30-700 IU/ml
- Weight is less than 150 kg (330 lbs)
- Allergic sensitization demonstrated by positive skin testing or in vitro testing for allergen-specific IgE to an allergen that is present year round (a perennial allergen), such as dust mite, animal dander,
## Policy Requirements

<table>
<thead>
<tr>
<th>Policy</th>
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<tbody>
<tr>
<td></td>
<td>cockroach, or molds</td>
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<td></td>
<td>Evidence of reversible disease (12% or greater improvement in FEV₁ with at least a 200-ml increase or 20% or greater improvement in PEF as a result of a short-acting bronchodilator challenge</td>
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<td>Patient should be non-smoking or actively receiving smoking cessation treatment</td>
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<td></td>
<td>Patient has tried and failed conventional immunotherapy or immunotherapy is not indicated. (Immunotherapy has demonstrated efficacy against dust mites, animal dander, and pollens but not against molds and cockroach allergies).</td>
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<td>Asthma symptoms are not adequately controlled by high dose inhaled corticosteroids AND a long-acting beta agonist (LABA) for 6 months</td>
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<td>o Inadequate control is defined as:</td>
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<td></td>
<td>▪ Requirement for systemic corticosteroids (oral, parenteral) to treat asthma exacerbations OR</td>
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<td></td>
<td>▪ Daily use of rescue medications (short-acting inhaled beta-2 agonists) OR</td>
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<td>▪ 2 ED visits or 1 hospitalization for asthma in the last 12 months OR</td>
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<td></td>
<td>▪ 2-3 unscheduled office visits with documentation of intensive care for acute asthma exacerbation OR</td>
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<td></td>
<td>▪ Nighttime symptoms occurring more than once a week</td>
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**For the treatment of chronic urticaria:**

- Symptoms continuously or intermittently present for at least 6 weeks.
- Prescribed by an allergist/immunologist or dermatologist
- 12 years of age or older
- Currently receiving H1 antihistamine therapy
- Failure of a 4 week, compliant trial of at least two high dose H1 antihistamines
  AND
- Failure of a 4-week, compliant trial of at least one of the following medications (used in addition to H1 antihistamine therapy):
### Policy Requirements

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<tr>
<th>AETNA BETTER HEALTH® OF NEW JERSEY</th>
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<td><strong>Policy</strong></td>
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- Leukotriene inhibitor (montelukast or zafirlukast)
- H2 antihistamine (ranitidine or cimetidine)
- Doxepin

**AND**

- Failure of a 4 week, compliant trial of low dose cyclosporine (used in addition to H1 antihistamine therapy) or contraindication to cyclosporine.

- **NOTE:** Anti-inflammatory medications (dapsone, sulfasalazine, or hydroxychloroquine) may be useful in treating urticaria, however the evidence is limited

**Note: Off-label and not covered for diagnosis of Allergic Rhinitis or food allergy**

### Zetia

Zetia requires step therapy with formulary HMG-CoA reductase inhibitors (i.e., statins) used for the treatment of hyperlipidemia for patients 10 years of age or older.

- If member has filled 2 prescriptions for a statin (e.g., simvastatin, atorvastatin, pravastatin) within the last 130 days, the prescription will automatically process at the pharmacy.
- Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.
- In those cases, Zetia will be authorized upon receipt of documentation to support the diagnosis of hyperlipidemia and failure of, or contraindication to formulary agents.

**Indefinitely**

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1. Acamprosate References
   3. Campral (acamprosate calcium) package insert. St. Louis, MO: Forest Pharmaceuticals, Inc

2. Afinitor References:

[ii] **Ampyra References**

[i] **Antidepressant References**

[ii] **ARBs References**

[iii] **Long-Acting Injectable Atypical Antipsychotics References:**
4. Zyprexa Relprevv [package insert]. Indianapolis, IN: LillyUSA, LLC: Revised 12/19/2014

[iii] Caprelsa References
2. Aetna CPB: Antineoplastics Accessed August 2015

[i] Cambia References

[i] CSF Agents
2. Larson, RA. Use of granulocyte colony stimulating factors in adult patients with chemotherapy-induced neutropenia and conditions other than acute leukemia, myelodysplastic syndrome, and hematopoietic cell transplantation. In: UpToDate, Drews, RE (Ed), Savarese, DMF (Ed), UpToDate, Waltham, MA. (Accessed on April 25, 2014.)
3. Friel, TJ, Scadden, DT. Hematologic manifestations of HIV infection: Neutropenia. In: UpToDate, Boxer, L (Ed), Tirnauer, JS (Ed), UpToDate, Waltham, MA. (Accessed on April 24, 2014.)
4. Berliner, N; Management of the adult with non-chemotherapy-induced neutropenia. In: UpToDate, Boxer, LA (Ed), Drews, RE (Ed), Tirnauer, JS (Ed), UpToDate, Waltham, MA. (Accessed on April 24, 2014.).


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1. Katkin, JP. Cystic fibrosis: Clinical manifestations and diagnosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on February 24, 2014).

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**Entyvio References**

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1. Epanova Package Insert. (2014, May 1). Wilmington, Delaware, USA.

**GnRH Agonists References**
16. Schenken, RS: Treatment of endometriosis. In UpToDate, Barbieri, RL (Ed), UpToDate, Waltham, MA, Jan 2013.
17. Saenger, P: Treatment of precocious puberty. In UpToDate, Snyder, PJ (Ed), UpToDate, Waltham, MA, April 2013.

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**Injectable Anticoagulants References**

**Lyrica References**
Neumega References


Northera References


Insulin Pen References:


Intravaginal Progesterone Products References

1. Norwitz, Errol R. Progesterone supplementation to reduce the risk of spontaneous preterm birth. In: UpToDate, Lockwood, Charles J (Ed), Barss, Vanessa A (Ed), UpToDate, Waltham, MA, Apr 8, 2015.

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3. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically

Platelet Inhibitors References:
5. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically
6. Effient (prasugrel) package insert. Indianapolis, IN: Eli Lilly and Company
8. (O’Gara, Kushner, & Ascheim, 2013)

Epanova References

Otezla References

Non-Calcium Based Phosphate Binder References

Promacta References

[a] Proton Pump Inhibitors References:
3. Fass R, Murthy U, Hayden CW, et al. Omeprazole 40 mg once a day is equally effective as lansoprazole 30 mg twice a day in symptom control of patients with gastroesophageal reflux disease (GERD) who are resistant to conventional-dose lansoprazole therapy-a prospective, randomized, multi-centre study. Aliment Pharmacol Ther. 2000; 14: 1595-1603.

[b] Modafinil/Nuvigil
2. Fosnocht, KM. Approach to the adult patient with fatigue. In: UpToDate, Fletcher, RH (Ed), UpToDate, Waltham, MA. (Accessed on August 15, 2014.)
3. Escalante, CP. Cancer-related fatigue: Treatment. In: UpToDate, Hesketh, PJ (Ed), UpToDate, Waltham, MA. (Accessed on August 15, 2014.)

[viii] Orencia References:

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1. Xeljanz (tacofitinib citrate) [package insert]. NJ, NJ; Pfizer Labs; Revised November 2012.

[11] Xolair References