



**PHARMACY MEDICAL POLICY**

**Policy #: 109**

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**Title**

**Medicare Advantage Prescription Drug Step Therapy Criteria**

**Note:** All requests for **outpatient retail pharmacy** for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the **Prior Authorization Form** on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients at (800)366-7778. Patients must have pharmacy benefits under their subscriber certificates.

**Description**

Step Therapy Policies for BCBSMA Medicare Advantage Products for the following drug categories:

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**When services are covered for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx plans; see below for coverage for these products**

### Step Therapy Criteria: Aldosterone Receptor Antagonists

Drug	Formulary Status	Step
• Spironolactone	Covered	1
• Spironolactone / HCTZ	Covered	1
• Inspra	Not Covered	2

**When services are covered:**

We cover Inspra (eplerenone) for patients who meet **one** of the following criteria:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of either spironolactone or spironolactone / hydrochlorothiazide combination by the patient within the previous 180 days.

**OR**

- The patient has a physician documented history of pre-existing gynecomastia.

**OR**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of Inspra by the patient within the previous 180 days.

**When services are not covered:**

We do not cover Inspra (eplerenone) when the above step therapy criteria are not met.

### Step Therapy Criteria: Angiotensin II Receptor Antagonists

Drug	Formulary Status	Step
• Avapro <sup>®</sup>	Covered	2
• Avalide <sup>®</sup>	Covered	2
• Diovan <sup>®</sup>	Covered	2
• Diovan HCT <sup>®</sup>	Covered	2
• Exforge <sup>®</sup>	Covered	2
• Atacand <sup>®</sup>	Not Covered	3
• Atacand HCT <sup>®</sup>	Not Covered	3
• Azor <sup>™</sup>	Not Covered	3
• Benicar <sup>®</sup>	Not Covered	3
• Benicar <sup>®</sup> HCT <sup>™</sup>	Not Covered	3
• Cozaar <sup>®</sup>	Not Covered	3
• Hyzaar <sup>®</sup>	Not Covered	3
• Micardis <sup>®</sup>	Not Covered	3
• Micardis HCT <sup>®</sup>	Not Covered	3
• Teveten <sup>®</sup>	Not Covered	3
• Teveten HCT <sup>®</sup>	Not Covered	3

**When services are covered:**

**We cover the angiotensin II receptor antagonists listed in the above chart in the following stepped approach:**

**Step 2:** Formulary Step 2 medications will be covered if the following criteria are met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a formulary Step 1 angiotensin converting enzyme inhibitor (ACE-I) or ACE-I-diuretic combination drug within the previous 180 days

**OR**

- The patient must have a physician documented diagnosis of Type 1 or Type 2 Diabetes Mellitus or have evidence of a BCBSMA paid claim for either insulin or an oral hypoglycemic drug within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of an Angiotensin II receptor blocker (ARB) or ARB-diuretic combination drug within the previous 180 days.

**Step 3:** Non-Formulary step 3 medications will be covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a formulary step 2 Angiotensin II receptor blocker (ARB) or ARB-diuretic combination drug within the previous 180 days.

**When services are not covered:**

**We do not cover** the medication listed in the chart above unless the above step therapy criteria are met.

**Step Therapy Criteria: Antidepressants**

<b>Drug</b>	<b>Formulary Status</b>	<b>Step</b>
• Bupropion	Covered	1
• Bupropion ER	Covered	1
• Bupropion SR	Covered	1
• Citalopram	Covered	1
• Fluoxetine	Covered	1
• Fluvoxamine	Covered	1
• Paroxetine	Covered	1
• Selfemra	Covered	1
• Sertraline	Covered	1
• Venlafaxine	Covered	1
• Cymbalta	Covered	2
• Effexor XR	Covered	2
• Pristiq	Covered	2
• Celexa	Not Covered	3
• Effexor	Not Covered	3
• Lexapro	Not Covered	3
• Luvox	Not Covered	3

• Luvox CR	Not Covered	3
• Paxil	Not Covered	3
• Paxil CR	Not Covered	3
• Pexeva	Not Covered	3
• Prozac	Not Covered	3
• Prozac Weekly	Not Covered	3
• Sarafem	Not Covered	3
• Wellbutrin	Not Covered	3
• Wellbutrin SR	Not Covered	3
• Wellbutrin XL	Not Covered	3
• Zoloft	Not Covered	3

**When services are covered:**

We cover the antidepressant medications listed in the chart above in the following stepped approach:

**Step 1:** Formulary Step 1 medications will be covered without prior authorization.

**Step 2:** Formulary Step 2 medications will be covered when **one** of the following criteria are met:

- The patient is < 18 years of age
- OR**
- There must be evidence of a BCBSMA paid claim by the patient of a Step 1 or Step 2 drug within the previous 180 days

**Note:** Cymbalta<sup>®</sup> will be covered for patients with diabetes who have a diagnosis of diabetic peripheral neuropathy when the following criteria are met:

- There must be evidence of a BCBSMA paid claim or physician documented use of insulin or an oral hypoglycemic medication within the previous 180 days.

**Step 3:** Non-Formulary Step 3 medications are covered when a formulary exception is submitted to BCBSMA Pharmacy Operations and when **one** of the following criteria are met:

- There must be evidence of a BCBSMA paid claim by the patient of either a Step 1 or Step 2 drug within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 3 drug within the previous 180 days.

**When services are not covered:**

We do not cover drugs listed unless the above step therapy criteria are met.

**Step Therapy Criteria: Antihyperlipidemics**

Drug	Formulary Status
<b>STEP 1</b>	Covered
• Lipitor 80mg	
• Lovastatin	
• Pravastatin	
• Simvastatin	Prior Use of Step 1 Required
<b>STEP 2</b>	
• Crestor	
• Vytorin	
• Zetia	Prior Use of Step1 and Step 2 Required
<b>STEP 3</b>	
• Lipitor (10, 20, 40mg)	Not Covered
<b>STEP 4 (Not Covered)</b>	
• Advicor	
• Altoprev	
• Caduet	
• Lescol	
• Lescol XL	
• Mevacor	
• Pravachol	
• Zocor	

**When services are covered:**

We cover the following antihyperlipidemics listed in the chart above in the following stepped approach:

**Step 1:** Formulary step 1 medications will be covered without prior authorization.

**Note:**

- Crestor (rosuvastatin) will pay at the point of sale without step therapy requirements when the prescription is written by a board certified/board eligible cardiologist or board certified/board eligible endocrinologist credentialed with Blue Cross Blue Shield of Massachusetts.
- Lipitor 80mg is covered as a step 1 drug for members who have had an Acute Coronary Syndrome.

**Step 2:** Formulary Step 2 medications will be covered when **one** of following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 1 drug by the patient within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim of a Step 2 drug by the patient within the previous 180 days.

**Step 3:** Formulary Step 3 medications will be covered when one of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 1 drug by the patient within the previous 180 days.

**AND**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 2 drug by the patient within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a Step 3 drug within the previous 180 days.

**Step 4: Non-formulary medications** are covered when a formulary exception request is submitted and approved by BCBSMA Pharmacy Operations and when the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 1 drug by the patient within the previous 180 days.

**AND**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 2 drug by the patient within the previous 180 days.

**AND**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 3 drug by the patient within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim of a Step 4 drug by the patient within the previous 180 days.

**When services are not covered:**

We do not cover drugs listed unless the above step therapy criteria are met.

**Step Therapy Criteria: Asthma Management**

Drug	Formulary Status
• Accolate	Step 2
• Advair Diskus	Step 2
• Advair HFA	Step 2
• Singulair	Step 2
• Symbicort	Step 2
• Zyflo CR	Step 2

**When services are covered:**

**We cover the asthma management medications listed in the chart above for new starts\* in the following stepped approach:**

\*New start is defined as no previous paid claim for the requested medication within the past 180 days.

**Step 2:** Accolate (zafirlukast), Advair Diskus (Fluticasone/Salmeterol), Advair HFA (Fluticasone/Salmeterol), Singulair (montelukast), Symbicort (Budesonide/Formoterol) and Zyflo CR (Zileuton) are covered when **one** of the following criteria are met:

- The patient has a physician documented diagnosis of asthma.

**OR**

- There must be evidence of a BCBSMA paid claim or physician documented use with any ONE of the following (excluding the use of samples): one inhaled corticosteroid, one inhaled beta<sub>2</sub> agonist, one inhaled mast cell stabilizer, one oral albuterol product or one oral theophylline containing product by the patient within the previous 180 days

**OR**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of the requested medication by the patient within the previous 180 days

**When services are not covered:**

We do not cover the above listed asthma management medications for allergies, allergic reactions, or chronic urticaria unless the above step therapy criteria are met.

### Step Therapy Criteria: Benign Prostatic Hyperplasia

Drug	Formulary Status	Step
• Finasteride	Covered	1
• Avodart	Not Covered	2
• Proscar	Not Covered	2

**When services are covered:**

**We cover the benign prostatic hyperplasia (BPH) medications** listed in the chart above for new starts\* in the following stepped approach

\*New start is defined as no previous paid claim for the requested medication within the past 180 days.

**Step 1: Step 1 medications** will be covered without prior authorization.

**Step 2: Step 2 medications** will be covered when **one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use (excluding the use of samples) by the patient of a step 1 drug within the previous 180 days

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a step 2 drug within the previous 180 days

**When services are not covered:**

We do not cover drugs listed in the above chart unless the above step therapy criteria are met.

### Step Therapy Criteria: Bisphosphonates

Drug	Formulary Status	Step
• Alendronate	Covered	1
• Fosamax Oral Solution	Covered	1
• Actonel	Covered	2
• Actonel w/Calcium	Covered	2
• Boniva	Not Covered	3
• Fosamax Tablet	Not Covered	3
• Fosamax Plus D	Not Covered	3

**When services are covered:**

**We cover the bisphosphonate medications** listed in the chart above for new starts\* in the following stepped approach

\*New start is defined as no previous paid claim for the requested medication within the past 180 days.

**Step 1: Step 1 medications** will be covered without prior authorization.

**Step 2: Step 2 medications** will be covered when **one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use (excluding the use of samples) by the patient of a step 1 drug within the previous 180 days

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a step 2 drug within the previous 180 days

**Step 3: Non-formulary medications** are covered when a formulary exception request is submitted and approved by BCBSMA Pharmacy Operations and when the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 1 drug by the patient within the previous 180 days.

**AND**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, of a Step 2 drug by the patient within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim of a Step 3 drug by the patient within the previous 180 days.

**When services are not covered:**

We do not cover drugs listed unless the above step therapy criteria are met.

**Step Therapy Criteria: Cox II Inhibitors**

Drug	Formulary Status	Step
• Celebrex	Covered	2

**When services are covered:**

**Arthritis:** We cover **Celebrex** for patients with documented rheumatoid arthritis or osteoarthritis, when any of the following are met:

- The patient is age 60 or older

**OR**

- The patient has one or more of the following risk factors:
  - History of gastrointestinal ulcer or bleeding
  - Thrombocytopenia
  - Inflammatory Bowel Disease
  - Concurrent treatment with oral or injectable corticosteroids
  - Concurrent treatment with anticoagulants such as warfarin, heparin, Lovenox, Fragmin, Innohep, Arixtra, or high-dose aspirin
  - Treatment with methotrexate, gold, Enbrel, Remicade, Humira, Kineret, sulfasalazine, azathioprine, cyclosporine, hydroxychloroquine, Arava, Cuprimine, misoprostol, Supartz, Synvisc, or Hyalgan in the last 6 months
  - Current treatment with drugs such as Plavix, Ticlid, Pletal, dipyridamole, Aggrenox, or Agrylin
  - Current treatment with drugs such as mesalamine, olsalazine, 6-mercaptopurine and balsalazide
  - Treatment failure with two previous traditional non-COX-II **prescription** NSAIDs in last 6 months.

**Polyposis:** We cover **Celebrex** for patients with documented **familial adenomatous polyposis**.

**When services are not covered:**

We do not cover **Cox II Inhibitor drugs** for off-label uses such as migraine headaches, or for some FDA-approved indications such as menstrual pain or acute pain. There are multiple alternative drugs that are covered for these conditions.

We do not cover **Cox II Inhibitor drugs** for patients who are on low dose aspirin therapy, unless therapy is warranted as outlined above.

For patient safety, we do not cover **Cox II Inhibitor drugs** for patients with any of the following conditions:

- Active peptic ulcer disease or bleeding
- Sulfa allergy (applies to celecoxib)
- Allergy to aspirin or NSAIDs
- Severe kidney or liver dysfunction
- Age less than 18
- Cardiovascular disease
- Congestive heart failure.

**Step Therapy Criteria: Diabetes**

Drug	Formulary Status
• Exubera	Prior Use of Step 1 Required
• Janumet	
• Januvia	

**When Services are Covered:**

We cover **second step agents for diabetes** listed in the chart above for new starts\* in the following stepped approach:

\*New start is defined as no previous paid claim for the requested medication within the past 180 days.

**Inhaled Insulin: (Exubera)** will be covered if the following criteria are met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of either injectable insulin or a first step oral hypoglycemic medication within the previous 180 days

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of Insulin Inhalation (Exubera) within the previous 180 days.

**Dipeptidyl Peptidase IV (DPP-IV) Inhibitors: (Janumet, Januvia)** will be covered if the following criteria are met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of either injectable insulin or a first step oral hypoglycemic medication within the previous 180 days

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of Janumet (Sitagliptin/Metformin) or Januvia (Sitagliptin) within the previous 180 days.

**When services are not covered:**

We do not cover drugs listed in the above chart unless the above step therapy criteria are met.

### Step Therapy Criteria: Hypnotics

Drug	Formulary Status	Step
• Zolpidem	Covered	1
• Zaleplon	Covered	1
• Lunesta	Covered	2
• Ambien	Not Covered	3
• Ambien CR	Not Covered	3
• Rozerem	Not Covered	3
• Sonata	Not Covered	3

**When services are covered:**

**We cover the hypnotic medications listed in the chart above for new starts\* in the following stepped approach:**

\*New start is defined as no previous paid claim for the requested medication within the past 180 days.

**Step 1: Formulary step 1 medications** will be covered without prior authorization.

**Step 2: Formulary step 2 medications** will be covered when **one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 1 drug within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a Step 2 drug within the previous 180 days.

**Step 3: Non-Formulary medications** are covered when formulary exception request is submitted and approved by BCBSMA Pharmacy Operations **and one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 1 drug within the previous 180 days.

**AND**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 2 drug within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a Step 3 drug within the previous 180 days.

**When services are not covered:**

We do not cover drugs listed in the above chart unless the above step therapy criteria are met.

### Step Therapy Criteria: Immune Modulating Drugs

Drug	Formulary Status
• Enbrel	Step Required
• Humira	Step Required
• Kineret	Step Required

**When services are covered:**

**We cover Enbrel® (etanercept) for:**

1. **Adults (18 years or older) with rheumatoid arthritis** (ICD-9-CM diagnosis code range 714.0-714.2) **or psoriatic arthritis** (ICD-9-CM diagnosis code 696.0), when **all** the following criteria are met:
  - A documented diagnosis of adult rheumatoid arthritis or psoriatic arthritis
  - Treatment or treatment failure with or contraindication to one oral or injectable DMARD agent within the past 6 months
  - The drug is prescribed by a board-certified or board eligible rheumatologist **or**
  - The patient had previous use of Enbrel® (etanercept) within the previous 180 days.
  
2. **Children (greater than 4 years) with juvenile rheumatoid arthritis** (ICD-9-CM diagnosis code range 714.30-714.32), polyarticular course, when **all** the following criteria are met:
  - A documented diagnosis of Juvenile rheumatoid arthritis
  - Treatment failure with or contraindication to methotrexate
  - The drug is prescribed by a board-certified or board eligible rheumatologist **or**
  - The patient had previous use of Enbrel® (etanercept) within the previous 180 days.
  
3. **Adults (18 years and older) ankylosing spondylitis** (ICD-9-CM diagnosis code 720.0), when **all** the following criteria are met:
  - A documented diagnosis of Ankylosing spondylitis
  - Treatment failure with one prescription NSAID within the past 6 months
  - The drug is prescribed by a board-certified or board eligible rheumatologist **or**
  - The patient had previous use of Enbrel® (etanercept) within the previous 180 days.

**We cover Humira™ (adalimumab) for:**

1. **Adults (18 years and older) with rheumatoid arthritis** (ICD-9-CM diagnosis code range 714.0-714.2), when **all** the following criteria are met:
  - A documented diagnosis of adult rheumatoid arthritis
  - Treatment or treatment failure with or contraindication to one oral or injectable DMARD agent within the past 6 months.
  - The drug is prescribed by a board-certified or board eligible rheumatologist **or**
  - The patient had previous use of Humira™ (adalimumab) within the previous 180 days.
  
2. **Adults (18 years and older) ankylosing spondylitis** (ICD-9-CM diagnosis code 720.0), when **all** the following criteria are met:
  - A documented diagnosis of Ankylosing spondylitis
  - Treatment failure with one prescription NSAID within the past 6 months
  - The drug is prescribed by a board-certified or board eligible rheumatologist **or**
  - The patient had previous use of Humira™ (adalimumab) within the previous 180 days.
  
3. **Adults (18 years and older) with Active Crohn's Disease** (ICD-9-CM diagnosis code range 555.0-555.9) when **all** the following criteria are met:
  - A documented diagnosis of Crohn's Disease
  - Treatment or treatment failure with or contraindication to 2 or more of the following drugs:
    - Corticosteroids (e.g. prednisone, prednisolone, methylprednisolone, budesonide)
    - 5-Aminosalicylates (e.g. sulfasalazine, mesalamine, olsalazine, balsalazide)
    - Immunosuppressants / Immunomodulators (e.g. 6-mercaptopurine, azathioprine, methotrexate)
  - The drug is prescribed by a board-certified or board eligible gastroenterologist **or**
  - The patient had previous use of Humira™ (adalimumab) within the previous 180 days.
  
4. **Children (4 years and older) with juvenile idiopathic arthritis** (ICD-9-CM diagnosis code range 714.30-714.32) when **all** the following criteria are met:

- A documented diagnosis of juvenile idiopathic arthritis
- Treatment failure with or contraindication to methotrexate
- The drug is prescribed by a board-certified or board eligible rheumatologist **or**
- The patient had previous use of Humira™ (adalimumab) within the previous 180 days.

**We cover Kineret® (anakinra) for:**

1. **Adults (18 years and older) with rheumatoid arthritis** (ICD-9-CM diagnosis code range 714.0-714.2), when **all** the following criteria are met:
  - A documented diagnosis of adult rheumatoid arthritis
  - Treatment or treatment failure with or contraindication to one oral or injectable DMARD agent within the past 6 months.
  - The drug is prescribed by a board-certified or board eligible rheumatologist **or**
  - The patient had previous use of Kineret® (anakinra) within the previous 180 days.

**When services are not covered:**

We do not cover the above drugs for other conditions not listed above.

**Step Therapy Criteria: Immunosuppressants used to Treat Psoriasis**

Drug	Formulary Status
• Enbrel	Step Required
• Humira	Step Required
• Raptiva	Step Required

**When services are covered:**

**We cover Raptiva (Efalizumab), Enbrel (Etanercept), Humira (Adalimumab) or Remicade (Infliximab)** for FDA- approved indications only when **all** the following criteria are met:

- Patient is ≥ 18 years of age for Raptiva (Efalizumab), Enbrel (Etanercept), Humira (Adalimumab) and Remicade (Infliximab)
- Patient has plaque psoriasis (ICD-9-CM 696.1), *and*
- Patient has tried and failed one course of systemic therapy for psoriasis within the last 6 months, such as, but not limited to:
  - methotrexate
  - azathioprine
  - acitretin
  - tacrolimus
  - cyclosporine
  - mycophenolate mofetil
  - 6-thioguanine
  - sulfasalazine
  - hydroxyurea
  - propylthiouracil
  - oral methoxsalen plus UVA light (PUVA) and
- The drug is being prescribed by a board-certified or board eligible dermatologist **or**
- The patient had previous use of Raptiva (Efalizumab), Amevive (Alefcept), Enbrel (Etanercept), Humira (Adalimumab) or Remicade (Infliximab) within the previous 180 days.

**When services are not covered:**

We do not cover Raptiva (Efalizumab), Enbrel (Etanercept), or Humira (Adalimumab) for patients when the above criteria are not met.

**Step Therapy Criteria: Proton Pump Inhibitors**

<b>Drug</b>	<b>Formulary Status</b>	<b>Step</b>
• Omeprazole	Covered	1
• Pantoprazole	Covered	1
• Protonix Granules	Covered	2
• Prevacid	Covered	2
• Aciphex	Not Covered	3
• Nexium	Not Covered	3
• Prilosec	Not Covered	3
• Protonix	Not Covered	3
• Zegerid	Not Covered	3

**When services are covered:**

We cover the Proton Pump Inhibitors listed in the chart above for new starts\* in the following stepped approach:

\*New start is defined as no previous paid claim for the requested medication within the past 180 days.

**Step 1:** Formulary step 1 medications will be covered without prior authorization.

**Step 2:** Non-Formulary step 2 medications are covered when a formulary exception request is submitted and approved by BCBSMA Pharmacy Operations **and one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 1 drug within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a Step 2 drug within the previous 180 days.

**Step 3:** Non-Formulary step 3 medications are covered when a formulary exception request is submitted and approved by BCBSMA Pharmacy Operations **and one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 1 drug within the previous 180 days.

**AND**

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 2 drug within the previous 180 days.

**OR**

- There must be evidence of a BCBSMA paid claim by the patient of a Step 3 drug within the previous 180 days.

**When services are not covered:**

We do not cover the drugs listed unless the above step therapy criteria are met.

**Step Therapy Criteria: CNS Stimulants and Psychotherapeutic Agents**

<b>Drug</b>	<b>Formulary Status</b>
• Dextroamphetamine	Covered
• Methamphetamine	Covered
• Desoxyn	Covered
• Provigil	Covered
• Strattera	Covered
• Dexedrine	Not Covered
• Dexedrine Spansules	Not Covered

**When services are covered:**

**We cover Dexedrine / Dexedrine Spansules (dextroamphetamine), Desoxyn (methamphetamine), or generics** when the patient meets the following criteria:

- The patient is < 17 years of age **or**
- The patient is ≥ 17 years of age and has a diagnosis of attention-deficit / hyperactivity disorder (ADHD): (ICD-9-CM diagnoses codes, 314.00-314.01) or Narcolepsy (ICD-9-CM diagnoses codes, 347.00-347.11) **or**
- The prescription is written by a psychiatrist, neurologist, or oncologist **or**
- The patient had prior use of dextroamphetamine or methamphetamine with the last 180 days.

**We cover Strattera (atomoxetine)** when the patient meets all of the following criteria:

- Patient is < 17 years of age **or**
- Patient has a diagnosis of ADHD (ICD-9-CM diagnoses codes, 314.00-314.01) **and**
- Has tried and failed one course of treatment with one of the following medications within the past 180 days: **or**
- methylphenidate (brands or generics)
- dexmethylphenidate (brand or generic)
- amphetamines (brands or generics)
- pemoline
- Has a history of stimulant drug abuse or other substance abuse **or**
- The prescription is written by a Psychiatrist **or**
- The patient had a prior use of Strattera within the previous 180 days.

**We cover Provigil (modafinil)** when the patient meets the following criteria:

- Patient is < 17 years of age **or**
- Patient has a diagnosis of narcolepsy (ICD-9-CM diagnoses codes, 347.00-347.11), obstructive sleep apnea / hypopnea syndrome (ICD-9-CM diagnoses codes, 780.51, 780.53, and 780.57), or shift work sleep disorder (ICD-9-CM diagnosis code, 307.45) **or**
- The prescription is written by a Neurologist, Psychiatrist, or Oncologist **or**
- The patient had prior use of Provigil within the previous 180 days.

**When services are not covered:**

We do not cover the above drugs for other conditions not listed above

**When services are not covered for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products**

Refer to individual drug for exclusion criteria.

**Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature, such as a history of treatment failure or intolerance. Physicians may send relevant clinical information for individual patients who do not meet the on line step therapy criteria for consideration to:

Blue Cross Blue Shield of Massachusetts  
Clinical Pharmacy Department  
25 Technology Place  
Hingham, MA 02043  
Tel: 1-800-366-7778  
Fax: 1-866-463-7700

**Policy update history**

New Policy, effective 1/1/2009. Posted to web site 7/1/09.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Blue Cross Blue Shield of Massachusetts Clinical Pharmacy Department  
 25 Technology Place, Hingham, MA 02043 Tel: 1-800-366-7778

**Fax to: Clinical Pharmacy Program: (866)463-7700**

**Medicare Part D Coverage Determination Request Form**

This form cannot be used to request:

- Medicare non-covered drugs, including barbiturates, benzodiazepines, fertility drugs, drugs prescribed for weight loss, weight gain or hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations).
- Medications requiring prior authorization for which drug-specific forms are required. [See <Part D plan website.>] OR [See links to plan websites at [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04\\_Formulary.asp](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp)]

Patient Information		Prescriber Information	
Patient Name:		Physician name:	
Member ID# :		Specialty and Provider #:	
DOB:	Sex(circle): M F	Fax:	Phone:
Diagnosis:	Allergies:	Contact person (first and last name):	

Medical Information		
Medication:	Strength and Route of Administration:	Frequency:
<input type="checkbox"/> New Prescription OR Date Therapy Initiated:	Expected Length of Therapy:	Qty:
Prescriber's Signature:		Date:

**Rationale for Exception Request or Prior authorization(FORM CANNOT BE PROCESSED WITHOUT REQUIRED EXPLANATION)**

- Alternate drug(s) contraindicated or previously tried, but with adverse outcome (eg, toxicity, allergy, or therapeutic failure)  
 → **Specify below:** (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug(s);
  - Complex patient with one or more chronic conditions (including, for example, psychiatric condition, diabetes) is stable on current drug(s); high risk of significant adverse clinical outcome with medication change  
 → **Specify below:** Anticipated significant adverse clinical outcome
  - Medical need for different dosage form and/or higher dosage  
 → **Specify below:** (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason
  - Request for formulary tier exception  
 → **Specify below:** (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome
- Other: \_\_\_\_\_ → Explain below

**REQUIRED EXPLANATION:**

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**Request for Expedited Review**

- REQUEST FOR EXPEDITED REVIEW [24 HOURS]  
 → BY CHECKING THIS BOX AND SIGNING ABOVE, I CERTIFY THAT APPLYING THE 72 HOUR STANDARD REVIEW TIME FRAME MAY SERIOUSLY JEOPARDIZE THE LIFE OR HEALTH OF THE MEMBER OR THE MEMBER'S ABILITY TO REGAIN MAXIMUM FUNCTION

CMS 0690