

**Tufts Health Plan Medicare Preferred
2010 Step Therapy**

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*** Step Therapy criteria apply to new starts only**

Step Therapy Topic: ADHD (Attention Deficit Hyperactivity Disorder) Medications

Effective Date: January 1, 2010

Please refer to the table below for medications subject to this policy

Step-1 Drugs These are available at the point-of-sale without restriction	Step-2 Drugs These drugs are available if a member has had a fill for TWO drugs in Step-1 or ONE drug in Step-2 in the previous 180 days
Adderall	<p style="text-align: center;">Daytrana[®] or Liquadd[™]</p>
Adderall XR	
amphetamine salt combo	
Concerta	
Desoxyn	
Dexedrine Spansules	
dexmethylphenidate HCl	
dextroamphetamine sulfate	
DextroStat	
Focalin	
Metadate CD	
Metadate ER	
Methylin	
Methylin ER	
methylphenidate	
methylphenidate ER	
Ritalin	
Ritalin LA	
Ritalin SR	
Adderall XR	<p style="text-align: center;">Focalin XR[®] or Vyvanse[®]</p>
Concerta	
Dexedrine Spansules	
Metadate CD	
Metadate ER	
Methylin ER	
methylphenidate ER	
Ritalin LA	
Ritalin SR	

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Step Therapy Criteria

The following stepped approach applies to attention deficit hyperactivity disorder (ADHD) medications covered by Tufts Health Plan:

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover medications on Step-2 if the following criteria are met:

- The Member has had a 30-day trial of **two (2)** Step-1 ADHD medications within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use.

OR

- The Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use of a Step-2 ADHD medication within the previous 180 days.

Step Therapy Topic: Antidepressants

Effective Date: January 1, 2008

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
budeprion SR	Step-1 These drugs are covered at the point-of-sale without restriction	Tier-1
budeprion XL		Tier-1
bupropion HCl		Tier-1
bupropion SR		Tier-1
bupropion XL		Tier-1
citalopram HBr		Tier-1
fluoxetine HCl		Tier-1
fluvoxamine		Tier-1
paroxetine HCl		Tier-1
paroxetine ER		Tier-1
Selfemra		Tier-1
sertraline		Tier-1
venlafaxine		Tier-1
Cymbalta	Step-2 These drugs are covered if a member has had a fill for a Step-1, Step-2 or Step-3 drug in the previous 180 days	Tier-3; DL*
Effexor XR		Tier-3
Lexapro		Tier-3
Pristiq		Tier-2
Venlafaxine ER 24hr		Tier-3
Celexa	Step-3 These drugs are covered if a member has had a fill for a Step-2 or Step-3 drug in the previous 180 days	Tier-3
Effexor		Tier-3
Emsam		Tier-3
Paxil		Tier-3
Paxil CR		Tier-3
Pexeva		Tier-3
Prozac		Tier-3
Prozac Weekly		Tier-3
Sarafem		Tier-3
Wellbutrin		Tier-3
Wellbutrin SR		Tier-3
Wellbutrin XL		Tier-3
Zoloft	Tier-3	

* Dispensing Limitation Applies

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover medications on Step-2 if the following criteria are met:

- The Member is under 18 years of age.

OR

- The Member has had a 30-day trial of a Step-1, Step-2 or Step-3 Antidepressant drug within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use.

Step-3: Tufts Health Plan may cover medications on Step-3 if the Member has had a 30-day trial of a Step-2 or Step-3 drug within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use.

Note: **Cymbalta** (duloxetine) may be covered for Members when the following criteria are met and a prior authorization request to Tufts Health Plan using the *Universal Pharmacy Medical Review Request Form* is submitted:

- For Diabetic Peripheral Neuropathic Pain
 1. Physician documented diagnosis of neuropathic pain including pain associated with diabetic peripheral neuropathy.
 2. The Member has failed standard medication treatment and/or pain management, including gabapentin.
- For Fibromyalgia
 1. Physician documented diagnosis of fibromyalgia.
 2. The Member has failed standard medication treatment and/or pain management, including gabapentin.

Note: Emsam (selegiline transdermal system) may be covered for Members with major depressive disorder when the following criterion is met and a prior authorization request to Tufts Health Plan using the *Universal Pharmacy Medical Review Request Form* is submitted:

- Physician-documented inability to tolerate or contraindication to oral formulations of antidepressant medications in this step therapy.

Limitations

1. The following quantity limitations for Cymbalta (duloxetine) apply:

Cymbalta 20mg	60 capsules per 30 days
Cymbalta 30mg	60 capsules per 30 days
Cymbalta 60mg	30 capsules per 30 days

Step Therapy Topic: Eplerenone
 Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
spironolactone	<u>Step-1</u> These drugs are covered at the point-of-sale without restriction	Tier-1
spironolactone / hydrochlorothiazide		Tier-1
eplerenone	<u>Step-2</u> This drug is covered if a member has had a fill for a Step-1 or Step-2 drug in the previous 180 days	Tier-1

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover eplerenone if the Member has had a 30-day trial of spironolactone or spironolactone/ hydrochlorothiazide within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use.

Step Therapy Topic: Insomnia Treatments

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
zaleplon	<u>Step-1</u> These drugs are covered at the point-of-sale without restriction (DLs apply)	Tier-1; DL*
zolpidem tartrate		Tier-1; DL
Lunesta	<u>Step-2</u> These drugs are covered if a member has had a fill for a Step-1 or Step-2 in the previous 180 days (DLs apply)	Tier-2; DL
Rozerem		Tier-2; DL

* DL = Dispensing Limitation Applies

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover medications on Step-2 if the following criterion is met:

- The Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of a Step-1 or Step-2 insomnia treatment within the previous 180 days.

OR

- The Member has a physician documented contraindication or intolerance to zaleplon or zolpidem.

Limitations

1. The following quantity limitations apply:

Ambien	30 tablets per 30 days
Ambien CR	30 tablets per 30 days
Lunesta	30 tablets per 30 days
Rozerem	30 tablets per 90 days
Sonata	14 capsules per 30 days
zaleplon	14 capsules per 30 days
zolpidem tartrate	30 tablets per 30 days

Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations and submit a formulary exception request for those Members requiring quantities greater than detailed above.

2. Exception requests for additional quantities of the drugs included in this program may be authorized in 12-month intervals.

Step Therapy Topic: Leflunomide

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
methotrexate	<u>Step-1</u> These drugs are covered at the point-of-sale without restriction (DLs apply)	Tier-1
Trexall		Tier-3
Rheumatrex		Tier-3
leflunomide	<u>Step-2</u> This drug is covered if a member has had a fill for a Step-1 or Step-2 in the previous 120 days (DLs apply)	Tier-1

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover leflunomide if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of a Step-1 or Step-2 drug within the previous 120 days.

Step Therapy Topic: Lipid-lowering Agents

Effective Date: January 1, 2008

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point-of-sale. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan Medicare Preferred for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
lovastatin	<u>Step-1</u> These drugs are covered at the point-of-sale without restriction	Tier-1
pravastatin		Tier-1
simvastatin		Tier-1
Crestor	<u>Step-2</u> These drugs are covered if a member has had a fill for a Step-1, Step-2 or Step-3 drug in the previous 180 days	Tier-2
Vytorin		Tier-2
Lescol	<u>Step-3</u> These drugs are covered if a member has had a fill for a Step-1, Step-2 or Step-3 drug in the previous 180 days	Tier-3
Lescol XL		Tier-3
Lipitor		Tier-3
Zetia		Tier-3

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan Medicare Preferred may cover medications on Step-2 if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan Medicare Preferred or physician documented use of a 30-day supply of a Step-1, Step-2 or Step-3 antihyperlipidemic within the previous 180 days.

Step-3: Tufts Health Plan Medicare Preferred may cover medications on Step-3 if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan Medicare Preferred or physician documented use of a 30-day supply of a Step-2 or Step-3 antihyperlipidemic within the previous 180 days.

Step Therapy Topic: Lyrica

Effective Date: January 1, 2009

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
gabapentin	<u>Step-1</u> These drugs are covered at the point-of-sale without restriction	Tier-1
Neurontin		Tier-3
Lyrica (pregabalin)	<u>Step-2</u> This drug is covered if a member has had a fill for a Step-1 or Step-2 drug in the previous 180 days	Tier-3

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Prescriptions for Lyrica will adjudicate at the point-of-service if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan Medicare Preferred or physician documented use of a 30-day supply a Step-1 or Step-2 drug within the previous 180 days.

Step Therapy Topic: Oral Bisphosphonates

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point of sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
alendronate	<u>Step-1</u> These drugs are covered at the point-of-sale without restriction	Tier-1
Fosamax oral solution		Tier-3
Actonel	<u>Step-2</u> These drugs are covered if a member has had a fill for a Step-1, Step-2 or Step-3 drug in the previous 180 days	Tier-3
Actonel with Calcium		Tier-3
Boniva		Tier-3

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover medications on Step-2 if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of Step-1 or Step-2 drug within the previous 180 days.

Step Therapy Topic: Proton Pump Inhibitors

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point of sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
omeprazole	<u>Step-1</u> This drug is covered at the point-of-sale without restriction (DLs apply)	Tier-1; DL*
lansoprazole	<u>Step-2</u> These drugs are covered if a member has had a fill for a Step-1 or Step-2 drug in the previous 180 days (DLs apply)	Tier-1; DL
pantoprazole		Tier-1; DL

* DL = Dispensing Limitation Applies

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover medications on Step-2 if the Member has had a 30-day trial of a Step-1 or Step-2 drug within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use.

OR

Physician documented use of an adequate trial of at least 14 days of Prilosec OTC[®] within the previous 180 days.

Note: For children below 13 years of age, Tufts Health Plan covers Prevacid and Nexium oral suspension without prior authorization. Dispensing limitations apply.

Limitations

1. The following quantity limitations apply:

Aciphex	90 tablets per 90 days
Kapidex	90 capsules per 90 days
lansoprazole	90 capsules per 90 days
Nexium	90 capsules/packets per 90 days
omeprazole 10mg, 20mg	180 capsules per 90 days
omeprazole 40mg	90 capsules per 90 days
pantoprazole	30 tablets per 30 days
Prevacid	90 capsules/packets per 90 days
Prevacid Solutab	90 solutabs per 90 days
Prilosec 10mg, 20mg capsules	180 capsules per 90 days
Prilosec 40mg capsules	90 capsules per 90 days
Prilosec packets	90 packets per 90 days
Protonix	90 tablets/packets per 90 days
Zegerid	90 capsules/packets per 90 days

Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations and submit a formulary exception request for those Members requiring quantities greater than detailed above.

Step Therapy Topic: Nuvigil® (armodafinil) or Provigil® (modafinil)

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point of sale.

Please refer to the table below for medications subject to this policy

Step-1 Drugs These are available at the point-of-sale without restriction	Step-2 Drugs This drug is available if a member has had a fill for a Step-1 or Step-2 drug in the previous 180 days
Adderall/Adderall XR	Nuvigil® or Provigil®
amphetamine salt combo	
Concerta	
Daytrana	
Desoxyn	
Dexedrine Spansules	
dexmethylphenidate HCl	
dextroamphetamine sulfate	
DextroStat	
Focalin/ Focalin XR	
Liquadd	
Metadate CD	
Metadate ER	
Methylin	
Methylin ER	
methylphenidate	
methylphenidate ER	
Ritalin	
Ritalin LA	
Ritalin SR	
Vyvanse	

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover medications on Step-2 if the Member has had a 30-day trial of a Step-1 or Step-2 drug within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Service:

Tufts Health Plan may authorize coverage of Nuvigil or Provigil for Members when the following criteria are met:

1. The Member has documented excessive daytime sleepiness associated with a documented diagnosis of narcolepsy

OR

2. The Member has documented excessive daytime sleepiness associated with a documented diagnosis of one of the following chronic medical conditions:

- Chronic Fatigue Syndrome
- Depression
- Multiple Sclerosis
- Obstructive Sleep Apnea/Hypopnea Syndrome
- Organic Brain Disorder
- Parkinson's Disease

EITHER 1 OR 2

AND

3. The Member has had a treatment failure, inability to tolerate or other medical contraindication to one or more Step-1 medications

Note: Tufts Health Plan does not consider generalized anxiety disorder (GAD) as a contraindication for treatment with a formulary alternative stimulant.

Step Therapy Topic: Pulmicort Respules for Members Over the Age of 18

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
Advair Diskus	<p align="center"><u>Step-1</u> These drugs are available at the point-of-sale without restriction (DLs apply)</p>	Tier-2; DL
Advair HFA		Tier-2; DL
Aerobid/Aerobid-M		Tier-3; DL
Alvesco		Tier-3; DL
Asmanex		Tier-2; DL
Azmacort		Tier-3; DL
Flovent Diskus		Tier-2; DL
Flovent HFA		Tier-2; DL
Pulmicort Flexhaler		Tier-3; DL
QVAR		Tier-2; DL
Symbicort		Tier-2; DL
Pulmicort Respules inhalation suspension * DL = Dispensing Limitation Applies	<p align="center"><u>Step-2</u> This drug is available if a member has had a fill for a Step-1 or Step-2 drug in the previous 180 days (DLs apply)</p>	Tier-2; DL

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover Pulmicort Respules inhalation suspension if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of a Step-1 or Step-2 agent within the previous 180 days.

Limitations

1. The following quantity limitations apply:

Advair Diskus	3 diskus per 90 days
Advair HFA	6 inhalers per 90 days
Aerobid / Aerobid-M	9 inhalers per 90 days
Alvesco 80 mcg	3 inhalers per 90 days
Alvesco 160 mcg	6 inhalers per 90 days
Asmanex (14 doses & 30 doses)	12 inhalers per 90 days
Asmanex (60 doses & 120 doses)	6 inhalers per 90 days
Azmacort	6 inhalers per 90 days
Flovent Diskus	6 diskus per 90 days
Flovent HFA	6 inhalers per 90 days
Pulmicort Flexhaler	6 inhalers per 90 days
Pulmicort Respules	180 vials per 90 days
QVAR	6 inhalers per 90 days
Symbicort	6 inhalers per 90 days

Step Therapy Topic: Xopenex Inhalation Solution

Effective Date: January 1, 2010

Pharmacy Coverage Overview

Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Providers must refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan for Members who do not meet the step therapy criteria at the point-of-sale.

Please refer to the table below for medications subject to this policy

Drug	2010 Step	2010 Tier
Xopenex HFA inhalation aerosol	<u>Step-1</u> These drugs are available at the point-of-sale without restriction (DLs apply)	Tier-3; DL*
albuterol inhalation solution		Tier-1; DL
ipratropium/albuterol inhalation solution		Tier-1; DL
Xopenex inhalation solution	<u>Step-2</u> This drug is available if a member has had a fill for a Step-1 or Step-2 drug in the previous 180 days (DLs apply)	Tier-3; DL

* DL = Dispensing Limitation Applies

Step Therapy Criteria

Step-1: Medications on Step-1 are covered without prior authorization.

Step-2: Tufts Health Plan may cover Xopenex inhalation solution if the Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of a Step-1 or Step-2 agent within the previous 180 days.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Service:

Tufts Health Plan may authorize the use of Xopenex (levalbuterol HCl) inhalation solution for Members who meet either of the following clinical criteria:

1. Members who are unable to tolerate albuterol secondary to a clinically significant cardiovascular effect as measured by pulse rate, blood pressure, and/or sympathetic nervous system symptoms

OR

2. Members who have cardiovascular disorders, hypertension, cardiac arrhythmias, convulsive disorders, hyperthyroidism, or diabetes mellitus

Limitations

1. The following quantity limitations apply:

albuterol inhalation solution	360 vials per 90 days or 9 dropper bottles per 90 days
ipratropium/albuterol inhalation solution	360 vials per 90 days
Xopenex HFA	6 inhalers per 90 days
Xopenex inhalation solution	270 vials per 90 days