



## CNS: Antiparkinsonian agents

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p>Amantadine capsule, tablet, solution</p> <p>Benzotropine tablet</p> <p>Bromocriptine capsule, tablet</p> <p>Cabergoline tablet</p> <p>Carbidopa/levodopa (Sinemet) tablet</p> <p>Carbidopa/levodopa extended release (Sinemet CR) tablet</p> <p>Carbidopa/levodopa/entacapone (Stalevo) tablet</p> <p>Carbidopa/Levodopa (Parcopa) ODT</p> <ul style="list-style-type: none"> <li>- 25mg-250mg: No restrictions/limitations</li> </ul> <p>Entacapone (Comtan) tablet</p> <p>Pramipexole (Mirapex) tablet</p> <p>Ropinirole (Requip) tablet</p> <p>Selegiline (Eldepryl) tablet, capsule</p> <p>Trihexyphenidyl tablet, vial</p> <p><b>Non-Preferred</b></p> <p>Carbidopa (Lodosyn) tablets</p> <ul style="list-style-type: none"> <li>- Continuity of care</li> <li>- Trial of carbidopa/levodopa (Sinemet)</li> </ul> <p>Carbidopa/Levodopa (Duopa) suspension</p> <ul style="list-style-type: none"> <li>- Prior Authorization</li> <li>- Diagnosis of advanced Parkinson's disease</li> <li>- Treatment of motor fluctuations in patients with a feeding tube</li> </ul> <p>Carbidopa/Levodopa (Parcopa) ODT</p> <ul style="list-style-type: none"> <li>- 10-100mg, 25-100mg</li> <li>- Continuity of care</li> <li>- Inability to swallow</li> <li>- Trial of carbidopa/levodopa non-ODT</li> </ul> <p>Carbidopa/Levodopa (Rytary) capsule</p> <ul style="list-style-type: none"> <li>- 90 day trial of carbidopa/levodopa ER (Sinemet CR) tablet</li> </ul> <p>Tolcapone (Tasmar) tablet</p> <ul style="list-style-type: none"> <li>- Continuity of care</li> <li>- Trial of entacapone (Comtan)</li> </ul> <p>Pramipexole (Mirapex) extended-release tablet</p> <ul style="list-style-type: none"> <li>- Clinical reason (OH, IN MCD only) supported by chart notes why after a trial non-ER pramipexole cannot be used</li> </ul>	None	<ul style="list-style-type: none"> <li>- No new drugs and no new data or evidence to alter preferred agents or criteria</li> </ul>	Approved



## CNS: Antiparkinsonian agents

Rotigotine (Neupro) patch

- Continuity of care
- Diagnosis of restless leg syndrome
  - o 30 day trial of ropinirole or pramipexole
- Diagnosis of Parkinson's disease
  - o 90 day trial of ropinirole or pramipexole

**Ropinirole** (Requip XL) extended-release tablet

- Diagnosis of Parkinson's disease
- Clinical reason (OH, IN MCD only) supported by chart notes why after a 30 day trial immediate release ropinirole cannot be used

Rasagiline (Azilect) tablet

- Continuity of care
- 90 day trial of bromocriptine, amantadine, carbidopa/levodopa, pramipexole, ropinirole, or selegiline

Selegiline (Zelapar) ODT

- Continuity of care
- Inability to swallow
- Clinical reason (OH, IN MCD only) supported by chart notes why after a 30 day trial selegiline non-ODT tablets cannot be used



## CNS: Antipsychotics - Atypicals

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p><b>Aripiprazole</b> (Abilify, Abilify Discmelt) tablet, solution, ODT</p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o 2mg: No PA required for 60 tablets/30 days</li> <li>o 5mg, 10 mg, 15mg, 20mg, 30mg: No PA required for 30 tablets/30 days</li> <li>o 1mg/mL: No PA required for 900 mL/30 days</li> <li>o Discmelt (10mg, 15mg): No restrictions</li> </ul> </li> <li>- IN: <ul style="list-style-type: none"> <li>o 2mg, 10mg, 15mg, 30mg: No PA required for 1 tablet/day</li> <li>o 5mg: No PA required for 1.5 tablets/day</li> <li>o 20mg: No PA required for 2 tablets/day</li> <li>o Discmelt (10mg, 15mg): No PA required for 2 tablets/day</li> <li>o 1mg/mL: No PA required for 30 mL/day</li> </ul> </li> </ul> <p>Aripiprazole extended-release injection (Abilify Maintena)</p> <ul style="list-style-type: none"> <li>- IN: No PA required for 1 injection/28 days, age ≥18 years</li> </ul> <p>Aripiprazole lauroxil extended-release injection (Aristada)</p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o 441mg/1.6 mL, 662 mg/2.4 mL, 882 mg/3.2 mL: No PA required</li> <li>o 1064 mg/3.9 mL: QL 1 injection/56 days</li> </ul> </li> <li>- IN: <ul style="list-style-type: none"> <li>o 441mg/1.6 mL, 662 mg/2.4 mL, 882 mg/3.2 mL: No PA required for 1 injection/28 days, age ≥18 years</li> <li>o 1064 mg/3.9 mL: No PA required for 1 injection/56 days, age ≥18 years</li> </ul> </li> </ul> <p>Asenapine (Saphris) sublingual tablet</p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o Continuity of care if quantity ≤60 tablets/30 days</li> <li>o Diagnosis of bipolar disorder (or mood disorder only for ages &lt;15 years), schizophrenia, or autism <ul style="list-style-type: none"> <li>▪ 60 day trial of aripiprazole (Abilify)</li> </ul> </li> </ul> </li> <li>- IN: No PA required for 2 tablets/day</li> </ul> <p><b>Clozapine</b> tablet</p> <ul style="list-style-type: none"> <li>- IN: <ul style="list-style-type: none"> <li>o 25mg, 50mg, 200mg: No PA required for 3 tablets/day</li> <li>o 100mg: No PA required for 6 tablets/day</li> </ul> </li> </ul> <p>Clozapine rapid-dissolve tablet (Fazaclo)</p> <ul style="list-style-type: none"> <li>- IN: Preferred in IN only. <ul style="list-style-type: none"> <li>o 12.5mg, 25mg, 150mg, 200mg No PA required for 3 tablets/day.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Add Zyprexa Relprevv to OH &amp; KY PDL as preferred agent</li> </ul>	<ul style="list-style-type: none"> <li>- OH &amp; KY PDL: Update Zyprexza Relprevv for consistency with UFF.</li> <li>- No new drugs and no new data or evidence to alter preferred agents or criteria</li> </ul>	Approved

## CNS: Antipsychotics - Atypicals

- 100mg: No PA required for 6 tablets/day
- Iloperidone (Fanapt) tablet, titration pack
  - OH & KY:
    - Continuity of care if quantity  $\leq 60$  tablets/30 days
    - Diagnosis of bipolar disorder (or mood disorder only for ages  $<15$  years), schizophrenia, or autism
      - 60 day trial of aripiprazole (Abilify)
  - IN: No PA required for 2 tablets day, age  $\geq 18$  years
- Lurasidone (Latuda) tablet
  - IN: Preferred in IN
    - 20mg, 40mg, 60mg, 120mg: No PA required for 1 tablet/day, age  $\geq 13$  years. New starts are limited to a 15-day supply. Ok to approve  $> 15$  days if there are paid claims for this drug in the last 120 days.
    - 80mg: No PA required for 2 tablets/day, age  $\geq 13$  years. New starts are limited to a 15-day supply. Ok to approve  $> 15$  days if there are paid claims for this drug in the last 120 days.
- Olanzapine (Zyprexa) tablet
  - OH & KY: No PA required for 30 tablets/30 days
  - IN:
    - 2.5mg, 5mg, 7.5mg: No PA required for 1 tablet/day
    - 10mg, 15mg: No PA required for 2 tablets/day
    - 20mg: No PA required for 3 tablets/day
- Olanzapine ODT (Zydis)
  - IN: Preferred in IN
    - 5mg: No PA required for 1 tablet/day
    - 10mg, 15mg: No PA required for 2 tablets/day
    - 20mg: No PA required for 3 tablets/day
- Olanzapine/fluoxetine (Symbiax) capsule
  - IN: No PA required for 1 capsule/day, age  $\geq 18$  years. New starts are limited to a 15-day supply. Ok to approve  $> 15$  days if there are paid claims for this drug in the last 120 days.
- Olanzapine injection (Zyprexa Relprevv)
  - OH & KY: Preferred. No restrictions
  - IN:
    - 210 mg, 300 mg: No PA required for 2 injections/28 days, age  $\geq 18$  years
    - 405 mg: No PA required for 1 injection/28 days, age  $\geq 18$  years

## CNS: Antipsychotics - Atypicals

### Paliperidone extended release (Invega) tablet

- OH & KY:
  - o 1.5 mg, 3 mg, 9 mg: No PA required for 30 tablets/26 days
  - o 6 mg: No PA required for 60 tablets/26 days
- IN:
  - o 1.5mg, 3mg, 9mg: No PA required for 1 tablet/day
  - o 6mg: No PA required for 2 tablets/day

### Paliperidone palmitate extended release injection (Invega Sustenna)

- IN: No PA required for 1 syringe/28 days

### Paliperidone palmitate extended release injection (Invega Trinza)

- IN: No PA required for 1 syringe/84 days

### Quetiapine (Seroquel) tablet

- OH & KY:
  - o 25 mg: No PA required for 120 tablets/30 days
  - o 50 mg, 100 mg: No PA required for 90 tablets/30 days
  - o 200 mg, 300 mg, 400mg: No PA required for 60 tablets/30 days
- IN:
  - o 25mg, 50mg, 100mg, 200mg: No PA required for 3 tablets/day
  - o 300mg, 400mg: No PA required for 4 tablets/day

### Quetiapine extended-release (Seroquel XR) tablet

- OH & KY: No PA required for 60 tablets/30 days
- IN:
  - o 50mg: No PA required for 2 tablets/day
  - o 150mg, 200mg: No PA required for 1 tablet/day
  - o 300mg: No PA required for 3 tablets/day
  - o 400mg: No PA required for 4 tablets/day

### Risperidone (Risperdal) tablet, solution, ODT

- IN:
  - o Solution: No PA required for 8 mL/day
  - o Tablet, ODT: No PA required for 2 tablets/day

### Risperidone long-acting injection (Risperdal Consta)

- OH & KY: No restrictions
- IN: No PA required for 2 syringes/28 days

### Ziprasidone (Geodon) capsule

- OH & KY: No PA required for 120 capsules/30 days
- IN:
  - o 20mg, 40mg: No PA required for 2 capsules/day, age ≥ 18 years.

## CNS: Antipsychotics - Atypicals

- 60mg, 80mg: No PA required for 3 capsules/day, age ≥18 years.

### Geodon vial

- OH & KY: No restrictions
- IN: 20 mg: No PA required for age ≥18 years

### Non-Preferred

#### Brexipiprazole (Rexulti) tablet

- OH & KY:
  - Continuity of care
  - Diagnosis of major depressive disorder
    - Concurrent therapy with formulary anti-depressants (i.e. escitalopram, citalopram, fluoxetine, paroxetine, fluvoxamine, sertraline, venlafaxine, venlafaxine ER, duloxetine, or bupropion)
    - 60 day trial of aripiprazole (Abilify)
  - Diagnosis of schizophrenia
    - 60 day trial of aripiprazole (Abilify)
- IN: Preferred in IN. No PA required for 1 tablet/day, age ≥18 years.

#### Cariprazine (Vraylar) capsule, therapy pack

- OH & KY:
  - Continuity of care if quantity ≤30 capsules/30 days
  - Diagnosis of bipolar I disorder or schizophrenia
  - 30 day trial of aripiprazole (Abilify)
- IN:
  - 1.5mg: No PA required for 2 capsules/day, age ≥18 years
  - 3mg, 4.5mg, 6mg: No PA required for 1 capsule/day, age ≥18 years
  - Dose pack 1.5 mg and 3 mg: No PA required for 1 pack/28 days

#### Clozapine rapid-dissolve tablet (Fazaclo)

- OH & KY:
  - Clinical reason (OH MCD only) supported by chart notes why after a trial clozapine tablets cannot be used

#### Clozapine suspension (Versacloz)

- Clinical reason (OH, IN MCD only) supported by chart notes why after a 30 day trial clozapine tablets cannot be used

#### Lurasidone (Latuda) tablet

- OH & KY:
  - Diagnosis of bipolar depression
    - Quantity limit: 30 tablets/30 days

## CNS: Antipsychotics - Atypicals

- *Diagnosis of schizophrenia*
  - *30 day trial of at least two of the following: aripiprazole, risperidone, clozapine, olanzapine, quetiapine IR or ER, or ziprasidone*
  - *Quantity limit: 30 tablets/30 days*
- Olanzapine ODT (Zydis)
  - *OH & KY:*
    - *Clinical reason (OH MCD only) supported by chart notes why after a trial olanzapine tablets cannot be used*
- Olanzapine/Fluoxetine (Symbyax) capsule
  - *OH & KY*
    - *Clinical reason (OH MCD only) supported by chart notes why after a trial fluoxetine and olanzapine cannot be used separately taken together*
  - *IN: Preferred in IN. No PA required for 1 capsule/day, age ≥18 years.*
- Pimavanserin (Nuplazid) tablet
  - *OH & KY:*
    - *Diagnosis of hallucinations or delusions associated with Parkinson's Disease psychosis*
      - *Prescribed by or in consultation with a neurologist, geriatrician, or psychiatrist*
      - *Member has tried and failed other atypical anti-psychotics (quetiapine, clozapine, or risperidone)*
      - *OR Physician has provided documentation showing member is not a candidate for quetiapine, clozapine, or risperidone*
  - *IN: No PA required for 2 tablets/day.*



## CNS: Antipsychotics - Miscellaneous

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p><b>Chlorpromazine</b> tablet</p> <ul style="list-style-type: none"> <li>- IN: No PA required for 4 tablets/day</li> </ul> <p><b>Fluphenazine</b> tablet, elixir, vial, dec vial, concentrate, injection</p> <ul style="list-style-type: none"> <li>- IN: <ul style="list-style-type: none"> <li>o Concentrate, elixir, dec vial, injection: No PA required for ages ≥18 years</li> <li>o Vial 2.5 mg/mL: Preferred, No PA</li> <li>o Tablet: No PA required for 4 tablets/day, age ≥18 years</li> </ul> </li> </ul> <p><b>Haloperidol</b> (Haldol) tablet, solution, concentrate, injection, ampule</p> <ul style="list-style-type: none"> <li>- IN: <ul style="list-style-type: none"> <li>o Decanoate Ampule 50 mg/mL, 100 mg/mL: No PA required for ages ≥18 years</li> <li>o Tablet: No PA required for 3 tablets/day</li> </ul> </li> </ul> <p><b>Loxapine</b> capsule</p> <ul style="list-style-type: none"> <li>- IN: No PA required for 4 capsules/day, ages ≥18 years</li> </ul> <p><b>Molindone</b> tablet</p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o Continuation of care</li> <li>o Dx: schizophrenia, dose up to 225 mg/day</li> </ul> </li> <li>- IN: <ul style="list-style-type: none"> <li>o 5mg, 10mg: No PA required for 4 tablets/day</li> <li>o 25mg: No PA required for 9 tablets/day</li> </ul> </li> </ul> <p><b>Perphenazine</b> tablet</p> <ul style="list-style-type: none"> <li>- IN: No PA required for 4 tablets/day, age ≥18 years</li> </ul> <p><b>Perphenazine/amitriptyline</b> tablet</p> <p><b>Pimozide</b> (Orap) tablet</p> <ul style="list-style-type: none"> <li>- IN: <ul style="list-style-type: none"> <li>o 1mg: No PA required for 10 tablets/day</li> <li>o 2mg: No PA required for 5 tablets/day</li> </ul> </li> </ul> <p><b>Prochlorperazine</b> (Compazine/Compro) tablet, injection, suppository</p> <p><b>Thioridazine</b> tablet</p> <ul style="list-style-type: none"> <li>- IN: No PA required for 4 tablets/day</li> </ul> <p><b>Thiothixene</b> capsule</p> <ul style="list-style-type: none"> <li>- IN: No PA required for 3 capsules/day</li> </ul> <p><b>Trifluoperazine</b> tablet</p> <ul style="list-style-type: none"> <li>- IN: <ul style="list-style-type: none"> <li>o 1mg, 2mg, 5mg: No PA required for 2 tablets/day</li> <li>o 10mg: No PA required for 4 tablets/day</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Add molindone to OH &amp; KY PDL</li> <li>- Add haloperidol oral concentrate to IN UFF</li> </ul>	<ul style="list-style-type: none"> <li>- OH &amp; KY PDL: Update molindone for consistency with UFF.</li> <li>- IN: Update haloperidol oral concentrate for consistency across the UFF and PDLs.</li> <li>- No new drugs and no new data or evidence to alter preferred agents or criteria</li> </ul>	Approved





## CNS: Antipsychotics - Miscellaneous

### Non-Preferred

Loxapine aerosol powder breath activated (Adasuve)

- *Clinical reason (OH, IN MCD only) supported by chart notes why after a 90 day trial aripiprazole tablets cannot be used*



## CNS: Attention Deficit Hyperactivity Disorder

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p><b>Amphetamine/dextroamphetamine mixed salts (Adderall) tablet</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o No PA required for 60 tablets/30 days</li> <li>o Continuity of care up to 60 mg daily dosing</li> <li>o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia up to 60 mg daily dosing</li> </ul> </li> <li>- IN: No PA required for 3 tablets/day</li> </ul> <p><b>Amphetamine/dextroamphetamine (Adderall XR) mixed salts extended-release capsule</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o No PA required for 60 tablets/30 days</li> <li>o Continuity of care up to 60 mg daily dosing</li> <li>o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia</li> </ul> </li> <li>- IN: <ul style="list-style-type: none"> <li>o 5mg, 10mg, 15mg: No PA required for 1 capsule/day</li> <li>o 20mg, 25mg, 30mg: No PA required for 2 capsules/day</li> </ul> </li> </ul> <p><b>Atomoxetine (Strattera) capsule</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o No PA required for 30 tablets/30 days</li> </ul> </li> <li>- IN: <ul style="list-style-type: none"> <li>o 10mg, 18mg, 25mg, 40mg: No PA required for 2 capsules/day</li> <li>o 60mg, 80mg, 100mg: No PA required for 1 capsule/day</li> </ul> </li> </ul> <p><b>Clonidine (Kapvay ER) extended-release tablet</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY: No PA required for 60 tablets/26 days</li> <li>- IN: No PA required for 4 tablets/day</li> </ul> <p><b>Dexmethylphenidate (Focalin) capsule, tablet</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o No PA required for 60 tablets/30 days</li> <li>o Continuity of care</li> <li>o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia</li> </ul> </li> <li>- IN: <ul style="list-style-type: none"> <li>o 2.5mg, 5mg: No PA required for 2 tablets/day</li> <li>o 10mg: No PA required for 4 tablets/day</li> </ul> </li> </ul>	None	- No new data or evidence to alter preferred agents or criteria	Approved

## CNS: Attention Deficit Hyperactivity Disorder

### Dexmethylphenidate (Focalin XR) extended-release capsule

- OH & KY:
  - o 5mg, 10mg, 15mg
    - No PA required for 60 capsules/30 days
    - Continuity of care
    - Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia
  - o 20mg, 25mg, 30mg, 35mg, 40mg
    - No PA required for 30 capsules/30 days
    - Continuity of care
    - Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia
- IN: No PA required for 1 capsule/day

### Dextroamphetamine extended-release (Dexedrine spansule) capsule

- OH & KY:
  - o No PA required for 30 capsules/30 days
  - o Continuity of care up to 60mg daily dosing
  - o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia and up to 60mg daily dosing
- IN: No PA required for 2 capsules/day

### Dextroamphetamine (Zenzedi) tablet – [see below for strengths that are not available as generic]

- OH & KY:
  - o No PA required for 60 tablets/30 days
  - o Continuity of care up to 60mg daily dosing
  - o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia and up to 60mg daily dosing
- IN:
  - o 5mg: No PA required for 1 tablet/day
  - o 10mg: No PA required for 4 tablets/day

### Guanfacine extended-release (Intuniv) tablet

- OH & KY:
  - o Continuity of care
- OH, KY, IN: No PA required for 30 tablets/30 days (1 tablet/day)

## CNS: Attention Deficit Hyperactivity Disorder

Lisdexamfetamine (Vyvanse) capsules, chewable tablets

- OH, KY, IN: No PA required for 30 capsules/30 days (1 capsule/day)
- Continuity of care up to 70mg daily dosing
- Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue, hypersomnia, or binge eating up to 70mg daily dosing

**Methylphenidate** (Ritalin, Methylin) tablets, chewable tablets, solution

- Tablets, chewable tablets: No PA required for 90 tablets/30 days (3 tablets/day)
- Solution
  - o 5mg/5mL: No PA required for 1800mL/30 days (60 mL/day)
  - o 10mg/5mL: No PA required for 900mL/30 days (30 mL/day)

**Methylphenidate ER** (Ritalin LA) extended release capsules

- OH & KY:
  - o No PA required for 30 capsules/30 days
  - o Continuity of care up to 60mg daily dosing
  - o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia up to 60mg daily dosing
- IN:
  - o 20mg, 40mg: No PA required for 1 capsules/day
  - o 30mg: No PA required for 2 capsules/day

**Methylphenidate ER** (Metadate CD) extended release capsules

- OH & KY:
  - o No PA required for 30 capsules/30 days
  - o Continuity of care up to 60mg daily dosing
  - o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia up to 60mg daily dosing
- IN: No PA required for 1 capsule/day

**Methylphenidate ER** (Metadate ER, Metadate ER, Ritalin SR) extended release tablets

- OH & KY:
  - o No PA required for 30 tablets/30 days
  - o Continuity of care up to 60mg daily dosing
  - o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia up to 60mg daily dosing
- IN: No PA required for 3 tablets/day

## CNS: Attention Deficit Hyperactivity Disorder

### Methylphenidate ER (Concerta) tablets

- OH & KY:
  - o No PA required for 30 tablets/30 days
  - o Continuity of care
  - o Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia up to 72mg daily dosing
  - o For brand name product requests [Concerta, nonpreferred]: Diagnosis of ADD/ADHD, autism, Asperger's, hyperkinetic syndrome, narcolepsy/cataplexy/sleep apnea/OSA/shift work/MS related daytime fatigue or hypersomnia
    - 90 day trial of methylphenidate ER (Actavis)
- IN:
  - o 18mg, 27mg: No PA required for 1 tablet/day
  - o 36mg, 54mg: No PA required for 2 tablets/day

### Non-Preferred

#### Amphetamine (Adzenys XR ODT) tablet

- OH & KY:
  - o Age  $\geq$  6 years
  - o Clinical reason (OH MCD only) supported by chart notes why after a 90 day trial dextroamphetamine-amphetamine (Adderall) or Adderall XR cannot be used
- IN:
  - o Preferred in IN. No PA required for 1 tablet/day.

#### Amphetamine (Evekeo) tablet

- OH & KY:
  - o 5mg, 10 mg: Trial of Dextroamphetamine-amphetamine (Adderall)
- IN:
  - o 5 mg: No PA required for 1 tablet/day
  - o 10 mg: No PA required for 6 tablets/day

#### Amphetamine (Dyanavel XR) suspension

- OH & KY:
  - o Age  $\geq$  6 years
  - o Clinical reason (OH MCD only) supported by chart notes why after a 90 day trial dextroamphetamine-amphetamine (Adderall) or Adderall XR cannot be used
- IN: No PA required for 8mL/day

## CNS: Attention Deficit Hyperactivity Disorder

### Dextroamphetamine-Amphetamine (Mydayis) capsules

- OH & KY:
  - o Age 13 or older
  - o Dx: ADHD
  - o OH MCD: clinical reason why after a 90-day of dextroamphetamine-amphetamine ER (Adderall XR) and a 90-day trial of methylphenidate ER cannot be used
  - o KY MCD: clinical reason why after a 30-day of dextroamphetamine-amphetamine ER (Adderall XR) and a 30-day trial of methylphenidate ER cannot be used
  - o QL: 30 capsules/26 days
  - o Max daily dose age 12-17: 25 mg
  - o Max daily dose age 18 and above: 50 mg
- IN:
  - o Age 13 or older
  - o Dx: ADHD
  - o Clinical reason why after a 90-day trial of dextroamphetamine-amphetamine ER (Adderall XR) and a 90-day trial of methylphenidate ER cannot be used
  - o QL: 30 capsules/26 days

### Dextroamphetamine solution (Procentra)

- OH & KY:
  - o Dx: ADD, ADHD Asperger's, Hyperkinetic syndrome
  - o Age 3-5
    - Clinical reason (OH only) supported by chart notes why after a 90 day trial of any combo of dextroamphetamine tablets (Dexedrine), amphetamine salt combo (ADDERALL), dextroamphetamine-amphetamine ER (ADDERALL XR)  
Note: capsules can be opened and sprinkled on a small amount of food
    - \*Up to 60MG total daily dosing
  - o Age 6 or older
    - Trial (90 days total) of any combo of: dextroamphetamine, dextroamphetamine ER (Dexedrine), amphetamine salt combo (ADDERALL), dextroamphetamine-amphetamine ER (ADDERALL XR), or Vyvanse Note: capsules can be opened and sprinkled on a small amount of food
    - \*Up to 60MG total daily dosing
- IN: Preferred in IN. No PA required for 40mL/day.

### Kapvay ER titration kit

- OH & KY:

## CNS: Attention Deficit Hyperactivity Disorder

<ul style="list-style-type: none"> <li>○ Clinical reason (OH MCD only) supported by chart notes why a trial of Clonidine SR (Kapvay ER) 0.1 mg tablet cannot be used</li> <li>- IN:             <ul style="list-style-type: none"> <li>○ No PA required for 4 tablets/day.</li> </ul> </li> </ul> <p><b>Methamphetamine (Desoxyn) tablets</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY:             <ul style="list-style-type: none"> <li>○ Continuity of care</li> <li>○ Diagnosis of ADD/ADHD, autism, Asberger's, or hyperkinetic syndrome with trial of:                 <ul style="list-style-type: none"> <li>▪ Ages 3-5 years: A 90-day total of any combo of dextroamphetamine, dextroamphetamine ER, amphetamine salt combo, dextroamphetamine-amphetamine ER</li> <li>▪ Ages 6 or older: A 90-day total of any combo of dextroamphetamine, dextroamphetamine ER, dexamethylphenidate, amphetamine salt combo, dextroamphetamine-amphetamine ER, methylphenidate ER, methylphenidate CR, methylphenidate SR, methylphenidate, Methylin ER, or Vyvanse</li> </ul> </li> </ul> </li> <li>- IN: Preferred in IN</li> </ul> <p><b>Methylphenidate (Daytrana) patches</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY:             <ul style="list-style-type: none"> <li>○ May approve if previously approved for Quillivant XR suspension Or</li> <li>○ Continuation of care</li> <li>○ Under 6 yo: 30-day trial of any combo of dextroamphetamine, dextroamphetamine ER (Dexedrine), amphetamine salt combo (ADDERALL), dextroamphetamine-amphetamine ER (ADDERALL XR)</li> <li>○ Age 6 and older: Clinical reason supported by chart notes why (after a 30 day trial of) Methylphenidate ER tablet (Concerta), Methylphenidate CD capsule (Metadate CD), Methylphenidate SR capsule (Ritalin LA) cannot be used</li> </ul> </li> <li>- IN:             <ul style="list-style-type: none"> <li>○ No PA required for 1 patch/day</li> </ul> </li> </ul> <p><b>Methylphenidate ER (Cotempla XR) ODT</b></p> <ul style="list-style-type: none"> <li>- OH &amp; KY:             <ul style="list-style-type: none"> <li>○ Age 6-17 yo                 <ul style="list-style-type: none"> <li>▪ 90-day trial (OH) or 30-day trial (KY) and failure to BOTH of the following preferred methylphenidate ER products: Ritalin LA and Metadate CD. OH also requires clinical reasons why those cannot be used</li> <li>▪ Also approve if previously approved for Quillivant XR or Quillichew</li> </ul> </li> </ul> </li> <li>- IN:             <ul style="list-style-type: none"> <li>○ Age 6-17 yo</li> </ul> </li> </ul>			
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## CNS: Attention Deficit Hyperactivity Disorder

- 90-day trial (OH) or 30-day trial (KY) and failure to BOTH of the following preferred methylphenidate ER products: Ritalin LA and Metadate CD. Clinical reasons why those cannot be used
- Also approve if previously approved for Quillivant XR or Quillichew
- QL 30 tablets/26 days

### Methylphenidate ER (Quillichew ER) chewable tablet

- OH & KY:
  - May approve if previously approved for Daytrana patches Or
  - Continuation of care
  - Under 6 yo: 30-day trial of any combo of dextroamphetamine, dextroamphetamine ER (Dexedrine), amphetamine salt combo (ADDERALL), dextroamphetamine-amphetamine ER (ADDERALL XR)
  - Age 6 and older: Clinical reason supported by chart notes why (after a 30 day trial of) Methylphenidate ER tablet (Concerta), Methylphenidate CD capsule (Metadate CD), Methylphenidate SR capsule (Ritalin LA) cannot be used
- IN:
  - 20 mg, 40 mg: No PA required for 1 tablet/day
  - 30 mg: No PA required for 2 tablets/day

### Methylphenidate ER (Quillivant XR) suspension

- OH & KY:
  - May approve if previously approved for Daytrana patches Or
  - Continuation of care
  - Under 6 yo: 30-day trial of any combo of dextroamphetamine, dextroamphetamine ER (Dexedrine), amphetamine salt combo (ADDERALL), dextroamphetamine-amphetamine ER (ADDERALL XR)
  - Age 6 and older: Clinical reason supported by chart notes why (after a 30 day trial of) Methylphenidate ER tablet (Concerta), Methylphenidate CD capsule (Metadate CD), Methylphenidate SR capsule (Ritalin LA) cannot be used
- IN:
  - 25 mg/5 mL: No PA required for 12 mL/day

### Zenzedi tablet

- OH & KY:
  - 2.5mg, 7.5mg, 15mg, 20mg, 30mg: Clinical reason (OH MCD only) supported by chart notes why after a 30 day trial dextroamphetamine (Zenzedi) 5mg or 10mg cannot be used
- IN:
  - 2.5 mg, 15 mg: No PA required for 1 tablet/day





## CNS: Attention Deficit Hyperactivity Disorder

- 7.5mg, 20 mg, 30 mg: No PA required for 2 tablets/day



## CNS: Fibromyalgia

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p><b>Duloxetine</b> (Cymbalta) capsules</p> <p><b>Gabapentin</b> (Neurontin) capsules, tablets</p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o 100mg: 1080 capsules/30 days</li> <li>o 300mg: 360 capsules, tablets/30 days</li> <li>o 400mg: 270 capsules/30 days</li> <li>o 600mg: 180 tablets/30 days</li> <li>o 800mg: 120 tablets/30 days</li> </ul> </li> <li>- IN: Quantity limits <ul style="list-style-type: none"> <li>o 300mg: 360 tablets/30 days</li> </ul> </li> </ul> <p><b>Pregabalin</b> (Lyrica)</p> <ul style="list-style-type: none"> <li>- OH &amp; KY: <ul style="list-style-type: none"> <li>o Continuity of care</li> <li>o Diagnosis of fibromyalgia, neuropathy, neuralgia, or sciatica <ul style="list-style-type: none"> <li>▪ 30 day trial of gabapentin at accepted daily doses of 1,200-2,400mg, amitriptyline, or duloxetine (include quantity/days)</li> </ul> </li> <li>o Diagnosis of seizure or epilepsy <ul style="list-style-type: none"> <li>▪ 30 day trial of one of the following: gabapentin, lamotrigine, divalproex, levetiracetam, levetiracetam ER, oxcarbazepine, carbamazepine, phenytoin, topiramate, valproic acid, or zonisamide</li> </ul> </li> <li>o Previously approved for and currently using Potiga, Banzel, Stavzor, Vimpat, or Onfi</li> </ul> </li> </ul> <p><b>Non-Preferred</b></p> <p><b>Milnacipran</b> (Savella)</p> <ul style="list-style-type: none"> <li>- OH &amp; KY <ul style="list-style-type: none"> <li>o Continuity of care</li> <li>o Diagnosis of fibromyalgia <ul style="list-style-type: none"> <li>▪ 30 day trial of: gabapentin at accepted daily doses of 1,200-2,400mg, amitriptyline, or duloxetine (include quantity/days)</li> </ul> </li> </ul> </li> <li>- IN: Preferred in IN</li> </ul>	None	<ul style="list-style-type: none"> <li>- No new data or evidence to alter preferred agents or criteria</li> </ul>	Approved



## CNS: Migraine

Current PDL	Recommended	Rationale	P&T Decision
<b>Ergotamine Derivatives</b> <b>Preferred</b> Dihydroergotamine injection (D.H.E. 45) Dihydroergotamine nasal spray (Migranal) - <i>Max 8 mL per 30 days</i> Ergotamine-Caffeine (Cafergot) 1-100mg - <i>Required Diagnosis= Prevention Of Vascular Headaches (Migraines) AND</i> - <i>A Trial Of At Least 2 Of The Following Drugs: Sumatriptan Tablets, Injection, Or Nasal Spray, Naratriptan, Rizatriptan, Almotriptan OR Dihydroergotamine Injection Or Nasal Spray OR Ergomar (Which Also Requires A PA)</i>  <b>Non-Preferred</b> Ergotamine-Caffeine (Migergot) suppository Ergotamine (Ergomar) sublingual tablet - <i>Required diagnosis = Migraine Prevention and a trial of Propranolol OR Topiramate</i> - <i>Required diagnosis = Migraine Abortion AND</i> <i>Age 6-17 Years Old: A One Time Trial Of Sumatriptan Tablets, Injection, Or Nasal Spray Or Rizatriptan</i> <i>Age 18 And Older: A One Time Trial Of At Least 2 Of The Following 4 Drugs: Sumatriptan Tablets, Injection, Or Nasal Spray, Naratriptan, Rizatriptan Or Almotriptan (Axert)</i>  <b>Selective Serotonin Agonists</b> <b>Preferred</b> Almotriptan (Axert) - <i>Max 12 tablets per month</i> Naratriptan (Amerge) - <i>Max 9 tablets per month</i> Rizatriptan (Maxalt) - <i>12 tablets per month</i> Rizatriptan ODT (Maxalt-MLT) - <i>Max 12 tablets per month</i> Sumatriptan - <i>Max 12 tablets per month</i> Sumatriptan injection - <i>Max 5 mL per month</i> Sumatriptan nasal spray - <i>Max 12 doses per month</i>	None	- No new data or evidence to alter preferred agents or criteria	Approved



## CNS: Migraine

### Non-Preferred

#### Frovatriptan (Frova)

- Age 6-17 Years Old = Must Try A One Time Trial Of Sumatriptan Tablets, Injection, Or Nasal Spray Or Rizatriptan OR
- Age 18 And Older = Must Try 2 Of The Following 3: Sumatriptan Tablets, Injection, Or Nasal Spray, Naratriptan, Rizatriptan Or Almotriptan (Axert)
- 12 per 30 day(s)

#### Sumatriptan Nasal powder (Onzetra)

- Age 18 And Older AND
- A Trial Of At Least 2 Of The Following 3 Drugs: Sumatriptan Tablets, Injection Or Nasal Spray, Naratriptan, Almotriptan, Or Rizatriptan

#### Eletriptan (Relpax)

- Ages 6-17 = Must Try A One Time Trial Of Sumatriptan Tablets, Injection, Or Nasal Spray Or Rizatriptan OR
- Ages 18 & Older = Must Try 2 Of The Following 3: Sumatriptan Tablets, Injection, Or Nasal Spray, Naratriptan, Rizatriptan Or Almotriptan

#### Sumatriptan/Naproxen (Treximet)

- Must try naproxen and sumatriptan separately taken together
- QL = 9 per 30 days

#### Sumatriptan subcutaneous auto-injector (Zembrace)

- Age= Between 18 And 65 Years Old
- Dx= Migraine Headaches
- Member Has Tried And Failed At Least One Of The Preferred Medications (Naratriptan, Rizatriptan, Zolmitriptan, Almotriptan Or Sumatriptan)
- Member Does Not Have ANY Of The Following Contraindications To Treatment:
  - o History Of Coronary Artery Disease Or Coronary Spasm
  - o Wolff-Parkinson-White Syndrome
  - o History Of Stroke, Transient Ischemic Attack, Or Hemiplegic, Or Basilar Migraine
  - o Peripheral Vascular Disease
  - o Ischemic Bowel Disease
  - o Uncontrolled Hypertension
- Age 6-17 Years Old: Must Try A One Time Trial Of Sumatriptan Tablets, Injection, Or Nasal Spray Or Rizatriptan
- Age 18 And Older: Must Try 2 Of The Following 3: Sumatriptan Tablets, Injection, Or Nasal Spray, Naratriptan, Rizatriptan Or Almotriptan (Axert)
- QL = 12 per 30 days

#### Zolmitriptan nasal spray (Zomig)



## CNS: Migraine

- *Must first try the following lower cost agent(s): sumatriptan nasal spray. Note: If above agent(s) fail after an one time trial, then this agent will be considered for coverage upon submission of a prior authorization form with proper documentation*

### Miscellaneous

#### Preferred

Acetaminophen/dichloralphenazone/isometheptene



## CNS: Multiple Sclerosis Agents

Current PDL	Recommended	Rationale	P&T Decision
<b>Preferred</b> Dalfampridine (Ampyra) tablet <ul style="list-style-type: none"> <li>- <i>Diagnosis of Multiple Sclerosis</i></li> <li>- <i>Member Has Been Currently Taking One Of The Following For The Last 90 Days: Avonex, Extavia, Glatopa (Copaxone), Betaseron, Plegridy, Rebif, Tysabri, Lemtrada, Gilenya, Tecfidera or Aubagio AND</i></li> <li>- <i>Member Is Able To Walk At A Baseline Of 25 Feet (T25FW) Between 8 And 45 Seconds</i></li> </ul> Dimethyl fumarate delayed release (Tecfidera) capsule <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul> Fingolimod (Gilenya) capsule <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul> Glatiramer acetate (Copaxone) injection <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul> Interferon Beta-1a (Avonex, Rebif) injection <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul> Interferon Beta-1b (Extavia) injection <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul> Teriflunomide (Aubagio) tablet <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul> Glatiramer acetate (Glatopa) injection <ul style="list-style-type: none"> <li>- <i>Diagnosis of relapsing Form of Multiple Sclerosis (RRMS and SPMS) Confirmed by Neurologist in Chart Notes</i></li> <li>- <i>Prescribed by, Or in Consultation with, a Neurologist or Under the Guidance of a Neurologist</i></li> </ul>	None	- No new data or evidence to alter preferred agents or criteria	Approved



## CNS: Multiple Sclerosis Agents

### Non-Preferred

#### Interferon Beta-1b (Betaseron)

- *Diagnosis of Multiple Sclerosis*
- *Prescribed By Or In Consultation With A Neurologist*
- *Member Has Had A 90 Day Trial With One Of The Following: Extavia, Avonex Or Glatopa (Copaxone) AND Experienced One Of The Following: Two Relapses, CNS Lesion Progression Or Worsening Disability Within The Past 12 Months*

#### Peginterferon Beta-1a (Plegridy) injection

- *Diagnosis Multiple Sclerosis*
- *Prescribed By Or In Consultation With A Neurologist*
- *Member Has Had A 90 Day Trial With ONE Of The Following: Extavia, Avonex Or Glatopa (Copaxone) AND Experienced One Of The Following: Two Relapses, CNS Lesion Progression Or Worsening Disability Within The Past 12 Months*

#### Daclizumab (Zinbrya) injection

- *Continuity of Care If Previously Approved By CareSource AND Member Has Not Experienced Two Relapses, CNS Lesion Progression Or Worsening Disability Within The Past 12 Months*
- *OR*
- *Diagnosis of Multiple Sclerosis*
- *Prescribed By Or In Consultation With A Neurologist*
- *Member Has Tried And Failed TWO Of The Following: Aubagio, Avonex, Betaseron, Glatopa (Copaxone), Extavia, Gilenya, Lemtrada, Plegridy, Rebif, Tecfidera, Or Tysabri*

#### Alemtuzumab (Lemtrada) infusion

- *Diagnosis of Multiple Sclerosis*
- *Prescribed By Or In Consultation With A Neurologist*
- *Member Has Had A 90 Day Trial With ONE Of The Following: Extavia, Avonex, Rebif, Betaseron, Plegridy, Or Glatopa (Copaxone) AND Experienced One Of The Following: Two Relapses, CNS Lesion Progression Or Worsening Disability Within The Past 12 Months*
- *AND*
- *Member Has Had A 90 Day Trial With An Oral Agent (Gilenya, Aubagio Or Tecfidera) AND Experienced One Of The Following: Two Relapses, CNS Lesion Progression Or Worsening Disability Within The Past 12 Months*
- *AND*
- *Member Has Had A 90 Day Trial With Tysabri AND Experienced One Of The Following: Two Relapses, CNS Lesion Progression Or Worsening Disability Within The Past 12 Months*



## CNS: Multiple Sclerosis Agents

Mitoxantrone (Novantrone) infusion

- OH, KY, IN:
  - o Member must be at least 18 years of age; AND
  - o Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
  - o Chart notes have been provided confirming diagnosis of Multiple Sclerosis based on McDonald Diagnostic Criteria; AND
  - o Member has documented trial and failure or contraindication to at least two formulary multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug); AND
  - o Member has documented Left Ventricular Ejection Fraction (LVEF) of greater than 50% in the chart notes within the last 3 months.
  - o Dosage allowed: 12 mg/m<sup>2</sup> infusion every 3 months (Maximum cumulative lifetime dose is 140 mg/m<sup>2</sup>)

Natalizumab (Tysabri) infusion

- OH & KY
  - o Relapsing-Remitting Multiple Sclerosis (RRMS), Secondary Progressive Multiple Sclerosis (SPMS)
    - Member must be between 18 and 65 years of age; AND
    - Medication must be prescribed by, or in consultation with, a neurologist or under the guidance of a neurologist; AND
    - Member has documentation in chart notes that member was tested for John Cunningham virus (JCV) with ELISA prior to initiating treatment; AND
    - Member has documented trial and failure or contraindication to at least two formulary multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).
    - Treatment failure requires at least 30 days of therapy for each agent without an adequate response.
    - Dosage allowed: 300 mg intravenous infusion over one hour every 4 weeks.
  - o Crohn's Disease
    - Medication is prescribed by a gastroenterologist; AND
    - Member must be at least 18 years or older moderate to severe Cohn's disease; AND
    - Member has documentation in chart notes that member was tested for John Cunningham virus (JCV) with ELISA prior to initiating treatment; AND
    - Medication is not being used in combination with immunosuppressant's or TNF-alpha inhibitors; AND



## CNS: Multiple Sclerosis Agents

<ul style="list-style-type: none"> <li>▪ Member has documented inadequate response or contraindication to trial of at least two different therapies for minimum of 30 days for each drug:             <ul style="list-style-type: none"> <li>• a) Corticosteroids (e.g. budesonide (Entocort), prednisone)); OR</li> <li>• b) Methotrexate (e.g. Rheumatrex); OR</li> <li>• c) Immunosuppressants (e.g. 6-mercaptopurine (Purinethol), Azathioprine (Imuran) or cyclosporine (Neoral, Sandimmune, Gengraf)); AND</li> </ul> </li> <li>▪ Member must have tried and failed at least 30 days of treatment with Humira.</li> <li>▪ Dosage allowed: 300 mg intravenous infusion over one hour every 4 weeks</li> </ul> <p>- IN</p> <ul style="list-style-type: none"> <li>○ Relapsing-Remitting Multiple Sclerosis (RRMS), Secondary Progressive Multiple Sclerosis (SPMS)             <ul style="list-style-type: none"> <li>▪ Diagnosis of a relapsing form of multiple sclerosis (RRMS and SPMS) confirmed by neurologist. Include chart notes.</li> <li>▪ Prescribed by, or in consultation with, a neurologist or under the guidance of a neurologist.</li> <li>▪ Member is negative for John Cunningham virus (JCV) with ELISA prior to initiating treatment and annually thereafter.</li> <li>▪ The member has had a trial with at least one of the following medications: Avonex, Betaseron, Copaxone/Glatopa, Extavia, Rebif, Aubagio, Gilenya, or Tecfidera, which was ineffective as Multiple Sclerosis defined above, not tolerated, or contraindicated.</li> </ul> </li> </ul> <p>Ocrevus (ocrelizumab)</p> <p>- OH &amp; KY:</p> <ul style="list-style-type: none"> <li>○ Primary Progressive Multiple Sclerosis (PPMS)             <ul style="list-style-type: none"> <li>▪ Member must be between 18 and 65 years of age; AND</li> <li>▪ Member must have evidence of at least one year of disease progression (worsening of neurological function without remission) documented in chart notes; AND</li> <li>▪ Medication must be prescribed by, or in consultation with, a neurologist or under the guidance of a neurologist; AND</li> <li>▪ Member must have two of the following:                 <ul style="list-style-type: none"> <li>• One or more MRI T2-weighted lesion(s) dissemination in space in the brain in periventricular, juxtacortical or infratentorial regions;</li> <li>• Two or more MRI T2-weighted lesions dissemination in space in lesions in the spinal cord;</li> </ul> </li> </ul> </li> </ul>			
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## CNS: Multiple Sclerosis Agents

- Evidence in the spinal fluid (and not in serum) of oligoclonal bands or an elevated IgG index; AND
  - Member must have documented negative results on Hepatitis B screening (negative results for both
  - HBsAg and anti-HBV). For patients who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult hepatologist and submit hepatologist's assessment for appropriateness of Ocrevus therapy before starting treatment; AND
  - Member has all necessary immunizations administered (according to immunization guidelines) at least 6 weeks prior to initiation of Ocrevus; AND
  - Member does not have an active infection; AND
  - Ocrevus is not been used in combination with other Multiple Sclerosis therapies (Note: When switching from drugs with prolonged immune effects, such as daclizumab, fingolimod, natalizumab, teriflunomide, or mitoxantrone, consider the duration and mode of action of these drugs because of additive immunosuppressive effects when initiating Ocrevus).
  - Dosage allowed: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.
- Relapsing-Remitting Multiple Sclerosis (RRMS), Secondary Progressive Multiple Sclerosis (SPMS)
  - Member must be between 18 and 65 years of age; AND
  - Member must have evidence of at least one year of disease progression (worsening of neurological function without remission) documented in chart notes; AND
  - Medication must be prescribed by, or in consultation with, a neurologist or under the guidance of a neurologist; AND
  - Member must have documented negative results on Hepatitis B screening (negative results for both HBsAg and anti-HBV). For patients who are negative for surface antigen (HBsAg) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult hepatologist and submit hepatologist's assessment for appropriateness of Ocrevus therapy before starting treatment; AND Member has all necessary immunizations administered (according to immunization guidelines) at least 6 weeks prior to initiation of Ocrevus; AND
  - Member does not have an active infection; AND
  - Ocrevus is not been used in combination with other multiple sclerosis therapies (Note: When switching from drugs with prolonged immune effects, such as daclizumab, fingolimod, natalizumab, teriflunomide, or mitoxantrone, consider



## CNS: Multiple Sclerosis Agents

<p>the duration and mode of action of these drugs because of additive immunosuppressive effects when initiating Ocrevus); AND</p> <ul style="list-style-type: none"> <li>Member has documented trial and failure or contraindication to at least two formulary multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).</li> <li>Dosage allowed: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion; then 600 mg intravenous infusion every 6 months.</li> </ul>			
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## CNS: Narcolepsy/Cataplexy

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p>Modafanil (Provigil) tablet</p> <ul style="list-style-type: none"> <li>OH &amp; KY: <ul style="list-style-type: none"> <li>Diagnosis of Narcolepsy/Cataplexy/Sleep Apnea/OSA/ Shift Work Disorder</li> </ul> </li> <li>IN: <ul style="list-style-type: none"> <li>No PA for 1 tablet per day</li> </ul> </li> </ul> <p>Armodafanil (Nuvigil) tablet</p> <ul style="list-style-type: none"> <li>OH &amp; KY: <ul style="list-style-type: none"> <li>Diagnosis of Narcolepsy/Cataplexy/Sleep Apnea/OSA/ Shift Work Disorder</li> </ul> </li> <li>IN: <ul style="list-style-type: none"> <li>No PA required for <ul style="list-style-type: none"> <li>50 mg: 2 tablets/day</li> <li>150 mg/200 mg/250 mg: 1 tablet/day</li> </ul> </li> </ul> </li> </ul> <p>Sodium Oxybate (Xyrem) solution</p> <ul style="list-style-type: none"> <li>OH &amp; KY: <ul style="list-style-type: none"> <li>Diagnosis narcolepsy with cataplexy with one of the below <ul style="list-style-type: none"> <li>Cerebrospinal fluid hypocretin-1 deficiency of less than 110 pg/mL or less than one-third of the normative values with the same standardized assay OR</li> <li>Sleep latency of less than 8 minutes and 2 or more sleep-onset rapid eye movement periods (SOREMPS) during a multiple sleep latency test (MSLT) OR</li> <li>One sleep-onset rapid eye movement period during the multiple sleep latency test (MSLT) and a sleep-onset rapid eye movement period (SOREMP) within 15 minutes of sleep onset during the polysomnography (PSG)</li> </ul> </li> <li>Diagnosis of narcolepsy without cataplexy with all of the below <ul style="list-style-type: none"> <li>Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months</li> </ul> </li> </ul> </li> </ul>	None	<ul style="list-style-type: none"> <li>No new data or evidence to alter preferred agents or criteria</li> </ul>	Approved



## CNS: Narcolepsy/Cataplexy

<ul style="list-style-type: none"> <li>▪ Mean sleep latency of less than 8 minutes and 2 or more sleep-onset rapid eye movement periods (SOREMPS) during a multiple sleep latency test (MSLT) OR</li> <li>▪ One sleep-onset rapid eye movement period during the multiple sleep latency test (MSLT) and a sleep-onset rapid eye movement period (SOREMP) within 15 minutes of sleep onset during the polysomnography (PSG)</li> <li>▪ Trial with Armodafinil (Nuvigil) or Modafinil (Provigil)</li> <li>▪ Trial with 1 of the following: Methylphenidate, Dextroamphetamine or Dextroamphetamine/Amphetamine</li> </ul> <p>- IN</p> <ul style="list-style-type: none"> <li>○ No PA required for 18 mL/day</li> </ul>			
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## Immunologic Agents: Biologic Disease Modifying Agents

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Biologic agents</b></p> <p><u>Preferred</u></p> <p>Adalimumab (Humira)</p> <ul style="list-style-type: none"> <li>- Diagnosis of Rheumatoid Arthritis (RA):             <ul style="list-style-type: none"> <li>○ OH &amp; KY:                 <ul style="list-style-type: none"> <li>▪ Member must be 18 years of age or older with moderate to severe active RA; AND</li> <li>▪ Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND</li> <li>▪ Medication must be prescribed by a rheumatologist; AND</li> <li>▪ Medication must be used in combination with methotrexate, or if intolerant to methotrexate, another</li> <li>▪ immunosuppressant (i.e. azathioprine, hydroxychloroquine, cyclosporine, etc.); AND</li> <li>▪ Member must have tried and failed treatment with at least two non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks.</li> </ul> </li> </ul> </li> </ul>	None	<ul style="list-style-type: none"> <li>- No new data or evidence to alter preferred agents or criteria</li> </ul>	Approved

## Immunologic Agents: Biologic Disease Modifying Agents

<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>▪ Dosage allowed: 40 mg subcutaneously every other week. Prior to any dosages or dosing frequencies greater than what is listed here medical necessity documentation must be supplied to justify coverage.</li> </ul> </li> <li>○ IN:           <ul style="list-style-type: none"> <li>▪ Member Is 18 Years Of Age Or Older With Moderately To Severely Active RA AND</li> <li>▪ Medication Was Prescribed By A Rheumatologist AND</li> <li>▪ Documented negative TB Test Within 6 Months Prior To Starting Therapy AND</li> <li>▪ Medication Must Be Used In Combination With Methotrexate, Or If Intolerant To Methotrexate, Another Immunosuppressant AND</li> <li>▪ Member Has Failed To Respond To At Least 12 Weeks Of, Two (2) Or More Non-Biologic DMARDs</li> <li>▪ Or Must Have Documented Contraindication To All Non-Biologic DMARDs.</li> <li>▪ Doseage Allowed: 40 mg subcutaneously every other week. Prior to any dosages or dosing frequencies greater than what is listed here medical necessity documentation must be supplied to justify coverage.</li> </ul> </li> </ul> </li> <li>- Diagnosis of Ankylosing Spondylitis (AS):       <ul style="list-style-type: none"> <li>○ OH &amp; KY:           <ul style="list-style-type: none"> <li>▪ Member must be 18 years of age or older; AND</li> <li>▪ Member must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND</li> <li>▪ Medication must be prescribed by a rheumatologist; AND</li> <li>▪ Member has had back pain for 3 months or more that began before the age of 45; AND</li> <li>▪ Current imaging results show an inflammation of one or both of the sacroiliac joints; AND</li> <li>▪ Member shows at least one of the following signs or symptoms of Spondyloarthritis:               <ul style="list-style-type: none"> <li>• Arthritis;</li> <li>• Elevated serum C-reactive protein;</li> <li>• Inflammation at the tendon, ligament or joint capsule insertions;</li> <li>• Positive HLA-B27 test;</li> <li>• Limited chest expansion;</li> <li>• Morning stiffness for 1 hour or more; AND</li> </ul> </li> <li>▪ Member meets at least one of the following scenarios:               <ul style="list-style-type: none"> <li>• Member has Axial (spinal) disease;</li> </ul> </li> </ul> </li> </ul> </li> </ul>			
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## Immunologic Agents: Biologic Disease Modifying Agents

- Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
  - Member has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response.
  - Dosage allowed: 40 mg subcutaneously every other week.
- IN:
  - Member Is 18 Years And Older AND
  - Medication Was Prescribed By Rheumatologist AND
  - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
  - Member Has Had At Least 3 Months Of Back Pain With Age Of Onset Of 45 Years Or Younger Documented In Chart AND
  - Current Imaging Results Show An Inflammation Of One Or Both Of The Sacroiliac Joints AND
  - Member Shows At Least One Of The Following Signs Or Symptoms Of Spondyloarthritis:
    - Arthritis
    - Elevated Serum C-Reactive Protein
    - Enthesitis (Eg, Inflammation Of Achilles Tendon Insertion)
    - Positive HLA-B27 Test
    - Limited Chest Expansion
    - Morning Stiffness For 1 Hour Or More AND
  - Member Meets At Least One Of The Following Scenarios:
    - Axial Spinal Disease Or
    - Peripheral Arthritis Without Axial Involvement And tried and failed treatment with at least 3 Months Of Sulfasalazine or Methotrexate AND
  - Member Failed 2 Or More NSAIDs At Maximum Recommended Doses Over A Period Of At Least 4 Weeks.
  - Dosage allowed: 40 mg every other week
- Diagnosis of Crohns' Disease (CD):
  - OH & KY:
    - Member is 6 years of age or older with moderate to severe active Crohn's disease.



## Immunologic Agents: Biologic Disease Modifying Agents

- *Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND*
- *Medication must be prescribed by a gastroenterologist; AND*
- *Member has had a documented trial and inadequate response to at least one of the following: 6-mercaptopurine, azathioprine, methotrexate or corticosteroids, OR*
- *Member has severe disease, as indicated by at least one of the following:*
  - *Esophageal or gastroduodenal disease;*
  - *Extensive small-bowel disease involving more than 100 cm;*
  - *History of colonic resection;*
  - *History of two or more small-bowel resections;*
  - *Perianal or rectal disease.*
- *Dosage allowed: Adult dose: 160 mg subcutaneously on day one, then 80 mg 2 week later, then 40 mg every other week beginning on day 29; Pediatric dose: 17 kg (37 lbs) to < 40 kg (88 lbs) induction dose: 80 mg initially on Day and 40 mg two weeks later (Day 15), maintenance: 20 mg every other week; ≥ 40 kg (88 lbs): 160 mg initially on Day 1 (given in one day or split over two consecutive days) and 80 mg two weeks later (Day 15), maintenance 40 mg every other week.*

○ *IN:*

- *Member Is 6 Years Of Age Or Older With Moderately To Severely Active Crohns' Disease AND*
- *Medication Was Prescribed By A Gastroenterologist*
- *Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND*
- *Documented Trial And Inadequate Response To 1 Or More Of The Following: 6-Mercaptopurine,*
- *Azathioprine, Methotrexate Or Corticosteroids OR*
- *Member Has Severe Disease, As Indicated By 1 Or More Of The Following:*
  - *Esophageal Or Gastroduodenal Disease*
  - *Extensive Small-Bowel Disease Involving More Than 100cm*
  - *History Of Colonic Resection*
  - *History Of Two (2) Or More Small-Bowel Resections*
  - *Perianal Or Rectal Disease.*

## Immunologic Agents: Biologic Disease Modifying Agents

- Dosage allowed: Adult dose: 160 mg subcutaneously on day one, then 80 mg 2 week later, then 40 mg every other week beginning on day 29; Pediatric dose: 17 kg (37 lbs) to < 40 kg (88 lbs) induction dose: 80 mg initially on Day and 40 mg two weeks later (Day 15), maintenance: 20 mg every other week; ≥ 40 kg (88 lbs): 160 mg initially on Day 1 (given in one day or split over two consecutive days) and 80 mg two weeks later (Day 15), maintenance 40 mg every other week.
- Diagnosis of Juvenile Idiopathic Arthritis (JIA):
  - OH & KY:
    - Member must be 2 years of age or older with moderate to severe active JIA; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist; AND
    - Member shows at least one of the following signs or symptoms:
      - Four or fewer joints involved with an adequate response to systemic corticosteroids (prednisone, cortisone, methylprednisolone, etc.) AND systemic immunosuppressants (azathioprine, cyclosporine, etc.) AND NSAID treatment for at least 12 weeks;
      - Five or more joints involved AND inadequate response to methotrexate;
      - Sacroiliitis AND inadequate response to methotrexate;
      - Uveitis with an inadequate response to systemic corticosteroids (prednisone, cortisone, methylprednisolone, etc.) AND systemic immunosuppressants (i.e. azathioprine, cyclosporine, etc.) AND topical ophthalmic corticosteroids (i.e. prednisolone, fluoromethalone, dexamethasone, etc.)
    - Dosage allowed: For members 10 to <15 kg: inject 10 mg subcutaneously every other week; For members 15 to <30 kg: inject 20 mg subcutaneously every other week; For members ≥ 30 kg: inject 40 mg subcutaneously every other week.
  - IN:
    - Member Is 2 Years Or Older With Moderately To Severely Active JIA AND
    - Medication Was Prescribed By Rheumatologist AND
    - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Member Shows At Least One Of The Following Signs Or Symptoms:



## Immunologic Agents: Biologic Disease Modifying Agents

- Four Or Fewer Joints Involved With An Inadequate Response To Systemic Corticosteroids AND
  - Systemic Immunosuppressants AND NSAIDs For At Least 12 Weeks
    - Five Or More Joints Involved And An Inadequate Response To Methotrexate
    - Sacroiliitis And An Inadequate Response To Methotrexate
    - Uveitis With An And Inadequate Response To Systemic Corticosteroids AND Systemic
  - Immunosuppressants AND Topical Ophthalmic Corticosteroids.
  - Dosage allowed: For members 10 to <15 kg: inject 10 mg subcutaneously every other week;
  - For members 15 to <30 kg: inject 20 mg subcutaneously every other week;
  - For members  $\geq 30$  kg: inject 40 mg subcutaneously every other week.
- Diagnosis of Psoriatic Arthritis (PsA):
  - OH & KY:
    - Member must be 18 years of age or older; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist or dermatologist; AND
    - Member meets at least one of the following scenarios:
      - Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence;
      - Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response;
      - Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID taken at the maximum recommended dosages.
  - IN:
    - Dosage allowed: 40 mg subcutaneously every other week.
    - Member Is 18 Years Of Age Or Older AND
    - Medication Was Prescribed By A Rheumatologist Or Dermatologist AND



## Immunologic Agents: Biologic Disease Modifying Agents

- Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
  - Member Meets At Least One Of The Following Scenarios:
    - Member Has Predominantly Axial Disease, As Indicated By Radiographic Evidence
    - Member Has Shown Symptoms Of Predominately Axial Disease That Has Lasted Longer Than 3
  - Months And An Inadequate Responses To At Least 4 Week Trials Of 2 Different NSAIDs Taken At the Maximum Recommended Dosages
    - Predominantly Non-Axial Disease And Member Has Failed To Respond After At Least An 8-Week
  - Trial Of Methotrexate AND NSAID Taken At The Maximum Recommended Dosages.
  - Dosage allowed: 40 mg subcutaneously every other week.
- Diagnosis of Plaque Psoriasis (PP):
- OH & KY:
    - Member must be 18 years of age or older; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist or dermatologist; AND
    - Member has plaque psoriasis involves 10% or more of the body surface area (BSA); AND
    - Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
    - Member has tried and failed to respond to treatment with at least one of the following:
      - At least 12 weeks of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
      - At least 12 weeks of phototherapy (i.e. UVB light therapy, Excimer laser treatments), tanning beds emit mostly UVA light and therefore would not meet this criteria).
      - At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
    - Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
    - Dosage allowed: Inject 80 mg subcutaneously, then 40 mg every other week beginning 1 week after the initial dose



## Immunologic Agents: Biologic Disease Modifying Agents

- IN:
  - Member Is 18 Years Of Age Or Older AND
  - Medication Was Prescribed By A Rheumatologist Or Dermatologist AND
  - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
  - Plaque Psoriasis Involving Ten (10) Percent Body Surface Area (BSA) Or More AND
  - Member's Psoriasis Area AND Severity Index (PASI) Score Is Greater Than Or Equal To 12 AND
  - Member Has Tried And Failed To Respond To Treatment With At Least One Of The Following:
    - At Least A 12 Week Trial Of Phototherapy Or Photochemotherapy
    - At Least A 4 Week Trial With Topical Antipsoriatic Therapy AND
  - Member Has Tried And Failed At Least A 12 Week Trial Of Treatment With An Immunosuppressant.
  - Dosage allowed: Inject 80 mg subcutaneously, then 40 mg every other week beginning 1 week after the initial dose.

### - Diagnosis of Ulcerative Colitis (UC):

- OH & KY:
  - Member is 18 years of age or older with moderate to severe, active ulcerative colitis; AND
  - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
  - Medication must be prescribed by a gastroenterologist; AND
  - Member has had a trial and inadequate response to at least one of the following:
    - 6-mercaptopurine;
    - Azathioprine;
    - Oral corticosteroids (i.e. prednisone, cortisone, methylprednisolone, etc.);
    - Salicylates (i.e. Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
  - Dosage allowed: Inject 160 mg subcutaneously on day one, then 80 mg 2 week later, then 40 mg every other week beginning on day 29.

- IN:
  - Member Is 18 Years Of Age Or Older With Moderately To Severely Active UC AND

## Immunologic Agents: Biologic Disease Modifying Agents

- Medication Was Prescribed By A Gastroenterologist AND
- Documented Negative Tb Test Within 6 Months Prior To Starting Therapy AND
- Member Failed To Respond To At Least One Of The Following: 6-Mercaptopurine, Azathioprine,
- Oral Corticosteroids Or Salicylates
- Dosage allowed: Inject 160 mg subcutaneously on day one, then 80 mg 2 week later, then 40 mg every other week beginning on day 29.
- Diagnosis of Uveitis (non-infectious, chronic):
  - OH & KY:
    - Medication must be prescribed by an ophthalmologist that is a uveitis specialist or an ocular immunologist; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Member has loss of visual acuity or has evidence of retinal involvement; AND
    - Member has tried at least a four week trial and has failed to respond to at least one of the following treatments:
      - Corticosteroids (prednisone, methylprednisolone, cortisone, etc.);
      - Systemic immunosuppressants (azathioprine, cyclosporine, etc.).
    - Dosage allowed: 80 mg as a single subcutaneous dose, then 40 mg every other week beginning 1 week after the initial dose.
  - IN:
    - Medication Was Prescribed By An Ophthalmologist That Is A Uveitis Specialist Or Ocular Immunologist AND
    - Documented Negative Tb Test Within 6 Months Prior To Starting Therapy AND
    - Member Has Tried At Least A Four Week Trial And Has Failed To Respond To Corticosteroids OR
    - Systemic Immunosuppressants AND
    - Member Has Loss Of Visual Acuity OR Evidence Of Retinal Involvement.
    - Dosage allowed: 80 mg as a single subcutaneous dose, then 40 mg every other week beginning 1 week after the initial dose.
- Diagnosis of Hidradenitis Suppurativa (HS):
  - OH & KY:
    - Member is 18 years of age or older with a diagnosis of moderate to severe hidradenitis suppurativa as defined by The Physicians Global Assessment Tool (Hurley Stage II or III); AND



## Immunologic Agents: Biologic Disease Modifying Agents

- Medication must be prescribed by a dermatologist; AND
- Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
- Member has made documented lifestyle changes that would promote weight loss if their body mass index (BMI) is greater than 25; AND
- Member has a documented negative Urine Nicotine Test; AND
- Member has tried at least a four week trial and has failed to respond to both of the following treatments:
  - Topical clindamycin and systemic tetracycline; AND
  - Systemic clindamycin and systemic rifampicin.
- Dosage allowed: 160 mg (given as four 40 mg injections on day 1 or given as two 40 mg injections per day over 2 consecutive days), then 80 mg 2 weeks later (day 15), then 40 mg every week beginning on day 29.

### ○ IN:

- Member Is 18 Years Of Age Or Older With Moderate To Severe Hidradenitis Suppurativa As Defined
- By The Physicians Global Assessment Tool (Hurley Stage II Or III) AND
- Medication Was Prescribed By A Dermatologist AND
- Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
- Member Has Made Documented Lifestyle Modifications That would promote weight loss If BMI Is
- Over 25 AND
- Documented Negative Urine Nicotine Test AND
- Member Has Tried And Failed At Least A 4 week Trial Of Both Of The Following Therapies;
  - Topical Clindamycin And Systemic Tetracycline AND
  - Systemic Clindamycin And Systemic Rifampicin.
- Dosage allowed: 160 mg (given as four 40 mg injections on day 1 or given as two 40 mg injections per day over 2 consecutive days), then 80 mg 2 weeks later (day 15), then 40 mg every week beginning on day 29.

### Etanercept (Enbrel)

- Diagnosis of Rheumatoid Arthritis (RA):
  - OH & KY:
    - Member must be 18 years of age or older with moderate to severe active RA; AND

## Immunologic Agents: Biologic Disease Modifying Agents

- *Member must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND*
- *Medication must be prescribed by a rheumatologist; AND*
- *Member must have tried and failed treatment with at least two non-biologic DMARDS OR must have a contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks (non-biologic DMARDS include: methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide).*
- *Dosage allowed: Inject 50 mg subcutaneously once weekly. Prior to any dosages or dosing frequencies greater than what is listed here medical necessity documentation must be supplied to justify coverage.*
- *IN"*
  - *Individual is 18 years of age or older*
  - *Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy*
  - *OR yearly for members with risk factors that are requesting continuation of therapy*
  - *Prescribed by a rheumatologist*
  - *Individual has failed to respond to at least 12 weeks of two (2) or more non-biologic DMARDS*
- *Diagnosis of Ankylosing Spondylitis (AS):*
  - *OH & KY:*
    - *Member must be 18 years of age or older with active ankylosing spondylitis; AND*
    - *Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND*
    - *Medication must be prescribed by a rheumatologist; AND*
    - *Member has had back pain for 3 months or more that began before the age of 45; AND*
    - *Current imaging results show an inflammation of one or both of the sacroiliac joints; AND*
    - *Member shows at least one of the following signs or symptoms of Spondyloarthritis:*
      - *Arthritis;*

## Immunologic Agents: Biologic Disease Modifying Agents

- Elevated serum C-reactive protein;
    - Inflammation at the tendon, ligament or joint capsule insertions;
    - Positive HLA-B27 test;
    - Limited chest expansion;
    - Morning stiffness for 1 hour or more; AND
  - 7. Member meets at least one of the following scenarios:
    - Member has Axial (spinal) disease;
    - Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
  - Member has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response.
  - Dosage allowed: Inject 50 mg subcutaneously once weekly. Prior to any dosages or dosing frequencies greater than what is listed here medical necessity documentation must be supplied to justify coverage.
- IN:
- Individual is 18 years of age or older with active AS
  - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
  - OR yearly for members with risk factors that are requesting continuation of therapy
  - Prescribed by a rheumatologist
  - Clinical and diagnostic imaging evidence of ankylosing spondylitis, as indicated by ALL of the following:
    - Back pain of 3 months or more duration and age of onset of 45 years or younger
    - Sacroiliitis on imaging
    - Spondyloarthritis signs or symptoms, as indicated by one (1) or more of the following:
      - Arthritis
      - Elevated serum C-reactive protein
      - Enthesitis (eg, inflammation of Achilles tendon insertion)
      - HLA-B27
      - Limited chest expansion
      - Morning stiffness for 1 hour or more

## Immunologic Agents: Biologic Disease Modifying Agents

- Disease activity and treatment scenario, as indicated by one (1) or more of the following:
  - Axial (spinal) disease
  - Peripheral arthritis without axial involvement, and failure of 3 or more months of therapy with sulfasalazine or methotrexate
- Failure of two (2) or more different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy
- Diagnosis of Juvenile Idiopathic Arthritis (JIA):
  - OH & KY:
    - Member must be 2 years of age or older with moderate to severe active JIA; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist; AND
    - Member shows at least one of the following signs or symptoms:
      - Four or fewer joints involved with an adequate response to systemic corticosteroids (prednisone, cortisone, methylprednisolone, etc.) AND systemic immunosuppressants (azathioprine, cyclosporine, etc.) AND NSAID treatment for at least 12 weeks;
      - Five or more joints involved and inadequate response to methotrexate;
    - Dosage allowed: For members <63 kg: inject 0.8 mg/kg (maximum dose 50 mg) subcutaneously once per week; for members ≥63 kg: inject 50 mg subcutaneously once per week.
  - IN:
    - Individual is two (2) years of age or older
    - Prescribed by a rheumatologist
    - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
    - OR yearly for members with risk factors that are requesting continuation of therapy
    - Joint involvement and treatment scenario includes one (1) or more of the following:
      - Four or fewer joints involved and inadequate response to ALL of the following:
        - Glucocorticosteroid injection





## Immunologic Agents: Biologic Disease Modifying Agents

- Methotrexate
  - NSAIDs after a 12-week trial
  - Five or more joints involved and inadequate response to methotrexate
- *Diagnosis of Plaque Psoriasis (PP):*
  - Member Is 4 Years Of Age Or Older AND
  - Medication Was Prescribed By A Rheumatologist Or Dermatologist AND
  - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
  - Plaque Psoriasis Involving Ten (10) Percent Body Surface Area (BSA) Or More AND
  - Member's Psoriasis Area AND Severity Index (PASI) Score Is Greater Than Or Equal To 12 AND
  - Member Has Tried And Failed To Respond To Treatment With At Least One Of The Following:
    - At Least A 12 Week Trial Of Phototherapy Or Photochemotherapy
    - At Least A 4 Week Trial With Topical Antipsoriatic Therapy AND
  - Member Has Tried And Failed At Least A 12 Week Trial Of Treatment With An Immunosuppressant.
  - Dosage allowed: Inject 50 mg subcutaneously twice weekly for 3 months then once weekly thereafter.
- *Diagnosis of Psoriatic Arthritis (PsA):*
  - OH & KY:
    - Member must be 18 years of age or older; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist or dermatologist; AND
    - Member meets at least one of the following scenarios:
      - Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence;
      - Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response;

## Immunologic Agents: Biologic Disease Modifying Agents

- Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and an NSAID.
  - Dosage allowed: Inject 50 mg subcutaneously once weekly. Prior to any dosages or dosing frequencies greater than what is listed here medical necessity documentation must be supplied to justify coverage.
- IN:
  - Individual is 18 years or older of age with active PsA
  - Prescribed by a rheumatologist or dermatologist
  - Moderate to severe active psoriatic arthritis, as indicated by one (1) or more of the following:
    - Predominantly axial disease (ie, sacroiliitis or spondylitis), as indicated by one (1) or more of the following:
      - Radiographic evidence of axial disease (eg, sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
      - Symptoms (eg, limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months duration, and unresponsive to trial of two (2) different NSAIDs
    - Predominantly non-axial disease
      - Individual has failed to respond after a least a 8-week trial of methotrexate and a trial of a NSAID

### Non-Preferred

#### Certolizumab pegol (Cimzia)

- Diagnosis of Crohns' Disease (CD):
  - OH & KY:
    - Member Is 18 Years Of Age Or Older With Moderately To Severely Active Crohns' Disease AND
    - Medication Was Prescribed By A Gastroenterologist AND
    - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Member Has Documented Trial And Failure Of Or Contraindication To Humira. Treatment Failure
    - Requires At Least 12 Weeks Of Therapy Without An Adequate Response.
    - Documented Trial And Inadequate Response To 1 Or More Of The Following: 6-Mercaptopurine, Azathioprine, Methotrexate Or Corticosteroids OR
    - Member Has Severe Disease, As Indicated By 1 Or More Of The Following:
      - Esophageal Or Gastroduodenal Disease

## Immunologic Agents: Biologic Disease Modifying Agents

- Extensive Small-Bowel Disease Involving More Than 100cm
  - History Of Colonic Resection
  - History Of Two (2) Or More Small-Bowel Resections
  - Perianal Or Rectal Disease.
- Dosage allowed: Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 400 mg every four weeks.
- Diagnosis of Rheumatoid Arthritis (RA):
  - OH & KY:
    - Member Is 18 Years Of Age Or Older With Moderately To Severely Active RA AND
    - Medication Was Prescribed By A Rheumatologist AND
    - Documented negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Member Has Failed To Respond To At Least 12 Weeks Of, Two (2) Or More Non-Biologic DMARDs Or Must Have Documented Contraindication To All Non-Biologic DMARDS AND
    - Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.
    - Dosage allowed: Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 200 mg every other week thereafter.
  - IN:
    - Individual is 18 years of age or older with moderately to severely active RA
    - Prescribed by a rheumatologist
    - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
    - OR yearly for members with risk factors that are requesting continuation of therapy
    - Individual has failed to respond to 12 weeks to two (2) or more non-biologic DMARDs
- Diagnosis of Psoriatic Arthritis (PsA):
  - OH & KY:
    - Member Is 18 Years Of Age Or Older AND
    - Medication Was Prescribed By A Rheumatologist Or Dermatologist AND
    - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Member Meets At Least One Of The Following Scenarios:
      - Member Has Predominantly Axial Disease, As Indicated By Radiographic Evidence

## Immunologic Agents: Biologic Disease Modifying Agents

- Member Has Shown Symptoms Of Predominately Axial Disease That Has Lasted Longer Than 3 Months And An Inadequate Responses To At Least 4 Week Trials Of 2 Different NSAIDs Taken At The Maximum Recommended Dosages
    - Predominantly Non-Axial Disease And Member Has Failed To Respond After At Least An 8-Week
    - Trial Of Methotrexate AND NSAID Taken At The Maximum Recommended Dosages AND
  - Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.
  - Dosage allowed: Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 200 mg every other week or 400 mg every four weeks.
- IN:
  - Age 18 years or older with moderate to severe active psoriatic arthritis
  - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
  - OR yearly for members with risk factors that are requesting continuation of therapy
  - Prescribed by a rheumatologist or dermatologist
  - Moderate to severe active psoriatic arthritis, as indicated by one (1) or more of the following:
    - 4.1 Predominantly axial disease (ie, sacroiliitis or spondylitis), as indicated by 1 or more of the following:
      - Radiographic evidence of axial disease (eg, sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
      - Symptoms (eg, limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months duration, and unresponsive to trial of two (2) different NSAIDs
    - Predominantly non-axial disease
      - Individual has failed to respond after at least an 8-week trial of methotrexate
      - and a trial of a NSAID
- Diagnosis of Ankylosing Spondylitis (AS):
  - OH & KY:
    - Member Is 18 Years And Older AND
    - Medication Was Prescribed By Rheumatologist AND



## Immunologic Agents: Biologic Disease Modifying Agents

- Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
- Member Has Had At Least 3 Months Of Back Pain With Age Of Onset Of 45 Years Or Younger Documented In Chart AND
- Current Imaging Results Show An Inflammation Of One Or Both Of The Sacroiliac Joints AND
- Member Shows At Least One Of The Following Signs Or Symptoms Of Spondyloarthritis:
  - Arthritis
  - Elevated Serum C-Reactive Protein
  - Enthesitis (Eg, Inflammation Of Achilles Tendon Insertion)
  - Positive HLA-B27 Test
  - Limited Chest Expansion
  - Morning Stiffness For 1 Hour Or More AND
- Member Meets At Least One Of The Following Scenarios:
  - Axial Spinal Disease Or
  - Peripheral Arthritis Without Axial Involvement And tried and failed treatment with at least 3 Months Of Sulfasalazine or Methotrexate AND
- Member Failed 2 Or More NSAIDs At Maximum Recommended Doses Over A Period Of At Least 4 Weeks AND
- Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.
- Dosage allowed: Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 200 mg every other week or 400 mg every four weeks.

### Golimumab (Simponi)

- Diagnosis of Ulcerative Colitis (UC):
  - o OH & KY:
    - Member Is 18 Years Of Age Or Older With Moderately To Severely Active UC AND
    - Medication Was Prescribed By Or In Consultant With A Rheumatologist AND
    - Documented Negative TB Test 6 Months Prior To Starting Therapy AND
    - Member must meet at least one (a, b or c) of the following:
      - Hospitalized With Fulminant Ulcerative Colitis
      - Member Hospitalized And After Three Days Of Intravenous Steroids Still Has A CRP Greater Than 45 Or More Than 8 Bloody Bowel Movements



## Immunologic Agents: Biologic Disease Modifying Agents

- Member Is Refractory To Or Requires Continuous Immunosuppression With Corticosteroids At A Dose Of Prednisone 40 To 60 Mg/Day (Or Equivalent), Cortisone, Methylprednisolone, Etc.) AND Is Refractory To Or Has A Contraindication To 5-Aminosalicylic Acid Agents AND Immunosuppressants (Azathioprine And 6-Mercaptopurine) AND
  - Member must have tried and failed treatment with Humira.
  - Dosage allowed: 200 mg subcutaneously at week 0, then 100 mg at week 3, followed by 100 mg every 4 weeks thereafter.
- Diagnosis of Rheumatoid Arthritis (RA):
- OH & KY:
    - Member Is 18 Years Of Age Or Older With Moderately To Severely Active RA AND
    - Medication Was Prescribed By A Rheumatologist AND
    - Documented negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Medication Must Be Used In Combination With Methotrexate, Or If Intolerant To Methotrexate, Another Immunosuppressant AND
    - Member Has Failed To Respond To At Least 12 Weeks Of, Two (2) Or More Non-Biologic DMARDs Or Must Have Documented Contraindication To All Non-Biologic DMARDS AND
    - Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.
    - Dosage allowed: 50 mg subcutaneously once a month.
  - IN:
    - Individual is 18 years of age or older with moderately to severely active RA
    - Prescribed by a rheumatologist
    - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
    - OR yearly for members with risk factors that are requesting continuation of therapy
    - Golimumab is given in combination with methotrexate or with another immunosuppressive agent if the individual is intolerant to methotrexate
    - Individual has failed to respond to 12 weeks of, to two (2) or more non-biologic DMARDs
- Diagnosis of Ankylosing Spondylitis (AS):
- OH & KY:



## Immunologic Agents: Biologic Disease Modifying Agents

- *Member Is 18 Years And Older AND*
  - *Medication Was Prescribed By Rheumatologist AND*
  - *Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND*
  - *Member Has Had At Least 3 Months Of Back Pain With Age Of Onset Of 45 Years Or Younger Documented In Chart AND*
  - *Current Imaging Results Show An Inflammation Of One Or Both Of The Sacroiliac Joints AND*
  - *Member Shows At Least One Of The Following Signs Or Symptoms Of Spondyloarthritis:*
    - *Arthritis*
    - *Elevated Serum C-Reactive Protein*
    - *Enthesitis (Eg, Inflammation Of Achilles Tendon Insertion)*
    - *Positive HLA-B27 Test*
    - *Limited Chest Expansion*
    - *Morning Stiffness For 1 Hour Or More AND*
  - *Member Meets At Least One Of The Following Scenarios:*
    - *Axial Spinal Disease Or*
    - *Peripheral Arthritis Without Axial Involvement And tried and failed treatment with at least 3 Months Of Sulfasalazine or Methotrexate AND*
  - *Member Failed 2 Or More NSAIDs At Maximum Recommended Doses Over A Period Of At Least 4 Weeks AND*
  - *Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.*
  - *Dosage allowed: 50 mg subcutaneously once a month.*
- *IN:*
- *Individual is 18 years of age or older*
  - *Prescribed by a rheumatologist*
  - *Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy*
  - *OR yearly for members with risk factors that are requesting continuation of therapy*
  - *Clinical and diagnostic imaging evidence of ankylosing spondylitis, as indicated by ALL of the following:*
    - *Back pain of 3 months or more duration and age of onset of 45 years or younger*

## Immunologic Agents: Biologic Disease Modifying Agents

- Sacroiliitis on imaging
  - Spondyloarthritis signs or symptoms, as indicated by one (1) or more of the following
    - Arthritis
    - Elevated serum C-reactive protein
    - Enthesitis (eg, inflammation of Achilles tendon insertion)
    - HLA-B27
    - Limited chest expansion
    - Morning stiffness for 1 hour or more
  - Disease activity and treatment scenario, as indicated by one (1) or more of the following:
    - Axial (spinal) disease
    - Peripheral arthritis without axial involvement, and failure of 3 or more months of therapy with sulfasalazine or methotrexate
  - Individual has failed to respond to, two (2) or more different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy
- Diagnosis of Psoriatic Arthritis (PsA):
- OH & KY:
    - Member Is 18 Years Of Age Or Older AND
    - Medication Was Prescribed By A Rheumatologist Or Dermatologist AND
    - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Member Meets At Least One Of The Following Scenarios:
      - Member Has Predominantly Axial Disease, As Indicated By Radiographic Evidence
      - Member Has Shown Symptoms Of Predominately Axial Disease That Has Lasted Longer Than 3 Months And An Inadequate Responses To At Least 4 Week Trials Of 2 Different NSAIDs Taken At The Maximum Recommended Dosages
      - Predominantly Non-Axial Disease And Member Has Failed To Respond After At Least An 8-Week Trial Of Methotrexate AND NSAID Taken At The Maximum Recommended Dosages AND
    - Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.
    - Dosage allowed: 50 mg subcutaneously once a month.
  - IN:



## Immunologic Agents: Biologic Disease Modifying Agents

- *Individual is 18 years of age or older*
- *Prescribed by a rheumatologist or dermatologist*
- *Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy*
- *OR yearly for members with risk factors that are requesting continuation of therapy*
- *Moderate to severe active psoriatic arthritis, as indicated by one (1) or more of the following:*
  - *Predominantly axial disease (ie, sacroiliitis or spondylitis), as indicated by one (1) or more of the following:*
    - *Radiographic evidence of axial disease (eg, sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)*
    - *Symptoms (eg, limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months duration, and unresponsive to trial of two (2) different NSAIDs*
  - *Predominantly non-axial disease*
    - *Individual has failed to respond after at least an 8-week trial of methotrexate and a trial of a NSAID*

### **Golimumab (Simponi Aria)**

- *Diagnosis of Rheumatoid Arthritis (RA):*
  - *OH & KY:*
    - *Member Is 18 Years Of Age Or Older With Moderately To Severely Active RA AND*
    - *Medication Was Prescribed By A Rheumatologist AND*
    - *Documented negative TB Test Within 6 Months Prior To Starting Therapy AND*
    - *Medication Must Be Used In Combination With Methotrexate, Or If Intolerant To Methotrexate, Another Immunosuppressant AND*
    - *Member Has Failed To Respond To At Least 12 Weeks Of, Two (2) Or More Non-Biologic DMARDs Or Must Have Documented Contraindication To All Non-Biologic DMARDS AND*
    - *Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel.*
    - *Dosage allowed: 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks.*

### **Infliximab (Remicade)**

- *Diagnosis of Crohn's Disease (CD):*



## Immunologic Agents: Biologic Disease Modifying Agents

- OH & KY:
  - Member Is 6-17 Years Of Age With Moderately To Severely Active CD As Defined By Pediatric Crohn's Disease Activity Index (PCDAI) Greater Than 30 OR Member Is 18 Years Of Age Or Older With Moderately To Severely Active Non-Fistulizing CD As Defined By Crohn's Disease Activity Index (CDAI) Greater Than 220 And Less Than 400 AND
  - Documented Trial And Inadequate Response To 1 Or More Of The Following: 6-Mercaptopurine, Azathioprine, Methotrexate Or Corticosteroids OR
  - Member Is 18 Years Of Age Or Older With Fistulizing CD AND
  - Medication Was Prescribed By A Gastroenterologist AND
  - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
  - Member Has Documented Trial And Failure Of Or Contraindication To Humira. Treatment Failure Requires At Least 12 Weeks Of Therapy Without An Adequate Response.
  - Dosage allowed: 5mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 6 weeks thereafter.
- Diagnosis of Ulcerative Colitis (UC):
  - OH & KY:
    - Member Is 6-17 Years Of Age With Moderate To Severe Active Ulcerative Colitis As Defined By Pediatric Ulcerative Colitis Activity Index (PUCAI) Of 35 Or Greater OR Member Is 18 Years Of Age Or Older With Moderately To Severely Active UC As Defined By Mayo Score Of 6 Or Greater With An Endoscopy Subscore Of 2 Or 3 AND
    - Medication Was Prescribed By A Gastroenterologist AND
    - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Documented Trial And Inadequate Response To 1 Or More Of The Following: 6-Mercaptopurine, Azathioprine, Methotrexate Or Oral Corticosteroids AND
    - Member Has Documented Trial And Failure Of Or Contraindication To Humira (Only For Members 18 Years Of Age Or Older). Treatment Failure Requires At Least 12 Weeks Of Therapy Without Adequate Response.
    - Dosage allowed: 5mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter.
- Diagnosis of Rheumatoid Arthritis
  - OH & KY:
    - Member Is 18 Years Of Age Or Older With Moderately To Severely Active RA AND
    - Medication Was Prescribed By A Rheumatologist AND



## Immunologic Agents: Biologic Disease Modifying Agents

- Documented negative TB Test 6 Months Prior To Starting Therapy AND
- Medication Is Given In Combination With Methotrexate Or With Another Immunosuppressive Agent If Member Is Intolerant To Methotrexate AND
- Member Has Failed To Respond To At Least 12 Weeks Of, Two (2) Or More Non-Biologic DMARDs Or Must Have Documented Contraindication To All Non-Biologic DMARDs AND
- Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel. Treatment Failure Requires At Least 12 Weeks Of Therapy Without An Adequate Response.
- Dosage allowed: 3 mg/kg at 0, 2, and 6 weeks, followed by 3 mg/kg every 8 weeks thereafter.

○ IN:

- Individual is 18 years of age or older with moderate to severe active RA
- Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
- OR yearly for members with risk factors that are requesting continuation of therapy
- Prescribed by a rheumatologist
- In combination with methotrexate or with another immunosuppressive agent if the individual is intolerant to methotrexate
- Individual has failed to respond to at least 12 weeks of two (2) or more non-biologic DMARDs

- Diagnosis of Ankylosing Spondylitis (AS):

○ OH & KY:

- Member Is 18 Years And Older AND
- Medication Was Prescribed By Rheumatologist AND
- Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
- Member Has Had At Least 3 Months Of Back Pain With Age Of Onset Of 45 Years Or Younger Documented In Chart AND
- Current Imaging Results Show An Inflammation Of One Or Both Of The Sacroiliac Joints AND
- Member Shows At Least One Of The Following Signs Or Symptoms Of Spondyloarthritis:
  - Arthritis
  - Elevated Serum C-Reactive Protein
  - Enthesitis (Eg, Inflammation Of Achilles Tendon Insertion)



## Immunologic Agents: Biologic Disease Modifying Agents

- Positive HLA-B27 Test
    - Limited Chest Expansion
    - Morning Stiffness For 1 Hour Or More AND
  - Member Meets At Least One Of The Following Scenarios:
    - Axial Spinal Disease Or
    - Peripheral Arthritis Without Axial Involvement And tried and failed treatment with at least 3 Months Of Sulfasalazine or Methotrexate AND
  - Member Failed 2 Or More NSAIDs At Maximum Recommended Doses Over A Period Of At Least 4 Weeks AND
  - Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel. Treatment Failure Requires At Least 12 Weeks Of Therapy Without An Adequate Response
  - Dosage allowed: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 6 weeks thereafter.
- IN:
- Individual is 18 years of age or older with active AS
  - Prescribed by a rheumatologist
  - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
  - OR yearly for members with risk factors that are requesting continuation of therapy
  - Clinical and diagnostic imaging evidence of ankylosing spondylitis, as indicated by ALL of the following:
    - Back pain of 3 months' or more duration and age of onset of 45 years or younger
    - Sacroiliitis on imaging
    - Spondyloarthritis signs or symptoms, as indicated by one (1) or more of the following:
      - Arthritis
      - Elevated serum C-reactive protein
      - Enthesitis (eg, inflammation of Achilles tendon insertion)
      - HLA-B27
      - Limited chest expansion
      - Morning stiffness for 1 hour or more
  - Disease activity and treatment scenario, as indicated by one (1) or more of the following:

## Immunologic Agents: Biologic Disease Modifying Agents

- Axial (spinal) disease
  - Peripheral arthritis without axial involvement, and failure of three (3) or more months of therapy with sulfasalazine or methotrexate
  - Individual has failed to respond to two (2) or more different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy
- Diagnosis of Psoriatic Arthritis (PsA):
  - OH & KY:
    - Member Is 18 Years Of Age Or Older AND
    - Medication Was Prescribed By A Rheumatologist Or Dermatologist AND
    - Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND
    - Member Meets At Least One Of The Following Scenarios:
      - Member Has Predominantly Axial Disease, As Indicated By Radiographic Evidence
      - Member Has Shown Symptoms Of Predominately Axial Disease That Has Lasted Longer Than 3 Months And An Inadequate Responses To At Least 4 Week Trials Of 2 Different NSAIDs Taken At The Maximum Recommended Dosages
      - Predominantly Non-Axial Disease And Member Has Failed To Respond After At Least An 8-Week Trial Of Methotrexate AND NSAID Taken At The Maximum Recommended Dosages AND
    - There Is Clinical Documentation That Treatment With Adalimumab (Humira) Or Etanercept (Enbrel) Was Not Effective After At Least A 12-Week Treatment Course.
  - IN:
    - Individual is 18 years of age or older with active PsA
    - Prescribed by a rheumatologist or dermatologist
    - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
    - OR yearly for members with risk factors that are requesting continuation of therapy
    - Moderate to severe active psoriatic arthritis, as indicated by one (1) or more of the following:
      - Predominately axial disease (ie, sacroiliitis or spondylitis), as indicated by one (1) or more of the following:

## Immunologic Agents: Biologic Disease Modifying Agents

- Radiographic evidence of axial disease (eg, sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
    - Symptoms (eg, limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration and unresponsive to trial of two (2) different NSAIDs
  - Predominately non-axial disease
    - Individual has failed to respond after at least a 8-week trial of methotrexate and a trial of a NSAID
- Diagnosis of Plaque Psoriasis (PP):
- OH & KY:
    - Member Is 18 Years Of Age Or Older AND
    - Medication was Prescribed By A Rheumatologist Or Dermatologist AND
    - Documented Negative TB Test 6 Months Prior To Starting Therapy AND
    - Member has plaque psoriasis for 6 months or longer; AND
    - Member Is Not Going To Receive No Concomitant Systemic Therapy Or Phototherapy While On Remicade AND
    - Member's Plaque Psoriasis Involving 10% Or More Of The Body Surface Area (BSA) Or 5% Or More Of BSA If Psoriasis Involves Sensitive Areas (Hands, Feet, Face, Or Genitals) AND
    - Member's Psoriasis Area And Severity Index (PASI) Greater Than Or Equal To 12 AND
    - Member Has Tried And Failed To Respond To Treatment With At Least One Of The Following:
      - At Least A 12 Week Trial Of Phototherapy Or Photochemotherapy
      - At Least A 4 Week Trial With Topical Antipsoriatic Therapy AND
    - Member Has Tried And Failed At Least A 12 Week Trial Of Treatment With An Immunosuppressant.
    - There Is Clinical Documentation That Treatment With Adalimumab (Humira) Or Etanercept (Enbrel) Was Not Effective After At Least A 12-Week Treatment Course.

### Ustekinumab (Stelara)

- Diagnosis of Plaque Psoriasis (PP):
  - OH & KY:
    - Member must be 18 years of age or older; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND

## Immunologic Agents: Biologic Disease Modifying Agents

- Medication must be prescribed by a rheumatologist or dermatologist; AND
  - Member has plaque psoriasis involves 10% or more of the member's body surface area; AND
  - Member has tried and failed treatment with both Enbrel and Humira; AND
  - Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
  - Member has tried and failed to respond to treatment with at least one of the following:
    - At least 12 weeks of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
    - At least 12 weeks of phototherapy (i.e. UVB light therapy, Excimer laser treatments; tanning beds emit mostly UVA light and therefore would not meet this criteria).
    - At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
  - Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
  - Dosage allowed: ≤ 100kg: 45mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter; ≥ 100kg: 90mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter.
- Diagnosis of Psoriatic Arthritis (PsA):
- OH & KY:
    - Member must be 18 years of age or older; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist or dermatologist; AND
    - Member has tried and failed treatment with both Enbrel and Humira; AND
    - Member meets at least one of the following scenarios:
      - Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence; OR
      - Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) and has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response; OR





## Immunologic Agents: Biologic Disease Modifying Agents

- Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and an NSAID.
- Dosage allowed: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter
- Diagnosis of Crohn's Disease (CD):
  - OH & KY:
    - Member is 18 years of age or older with moderate to severe, active Crohn's disease with demonstrated corticosteroid dependence; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a gastroenterologist; AND
    - Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response; AND
    - Member has had a document inadequate response to 6-mercaptopurine, azathioprine or
    - methotrexate; OR
    - Member has severe esophageal or gastroduodenal disease; OR
    - Member has extensive small-bowel disease involving more than 100 cm; OR
    - Member has a history of colonic resection; OR
    - Member has a history of two or more small bowel resections; OR
    - Member has perianal or rectal disease.
    - Dosage allowed: Induction: 260 mg - 520 mg (depending on weight) intravenously as a single dose then 8 weeks after induction dose, 90 mg subcutaneously every eight weeks.

## Secukinumab (Cosentyx)

- *Diagnosis of Ankylosing Spondylitis (AS):*
  - o *OH & KY:*
    - *Member Is 18 Years And Older AND*
    - *Medication Was Prescribed By Rheumatologist AND*
    - *Documented Negative TB Test Within 6 Months Prior To Starting Therapy AND*
    - *Member Has Had At Least 3 Months Of Back Pain With Age Of Onset Of 45 Years Or Younger Documented In Chart AND*
    - *Current Imaging Results Show An Inflammation Of One Or Both Of The Sacroiliac Joints AND*





## Immunologic Agents: Biologic Disease Modifying Agents

- Member Shows At Least One Of The Following Signs Or Symptoms Of Spondyloarthritis:
  - Arthritis
  - Elevated Serum C-Reactive Protein
  - Enthesitis (Eg, Inflammation Of Achilles Tendon Insertion)
  - Positive HLA-B27 Test
  - Limited Chest Expansion
  - Morning Stiffness For 1 Hour Or More AND
- Member Meets At Least One Of The Following Scenarios:
  - Axial Spinal Disease Or
  - Peripheral Arthritis Without Axial Involvement And tried and failed treatment with at least 3 Months Of Sulfasalazine or Methotrexate AND
- Member Failed 2 Or More NSAIDs At Maximum Recommended Doses Over A Period Of At Least 4 Weeks AND
- Member Has Documented Trial And Failure Of Or Contraindication To Humira And Enbrel. Treatment Failure Requires At Least 12 Weeks Of Therapy Without An Adequate Response.
- Dosage allowed: 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.

- Diagnosis of Plaque Psoriasis (PP):

o OH & KY:

- Member must be 18 years of age or older; AND
- Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
- Medication must be prescribed by a rheumatologist or dermatologist; AND
- Member ha plaque psoriasis involves 10% or more of the member's body surface area; AND
- Member has tried and failed treatment with both Enbrel and Humira; AND
- Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
- Member has tried and failed to respond to treatment with at least one of the following:
  - At least 12 weeks of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);

## Immunologic Agents: Biologic Disease Modifying Agents

- At least 12 weeks of phototherapy (i.e. UVB light therapy, Excimer laser treatments) (tanning beds emit mostly UVA light and therefore would not meet this criteria).
  - At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
- Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
- Dosage allowed: 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks
- Diagnosis of Psoriatic Arthritis (PsA):
  - OH & KY:
    - Member must be 18 years of age or older; AND
    - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
    - Medication must be prescribed by a rheumatologist or dermatologist; AND
    - Member has tried and failed treatment with both Enbrel and Humira; AND
    - Member meets at least one of the following scenarios:
      - Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence; OR
      - Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response; OR
      - Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and an NSAID.
  - Dosage allowed: With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter; without a loading dosage is 150 mg every 4 weeks.

### Abatacept (Orencia)

- Diagnosis of Juvenile Idiopathic Arthritis (JIA):
  - OH & KY:
    - Member must be 2 years of age or older with moderate to severe active JIA; AND

## Immunologic Agents: Biologic Disease Modifying Agents

- Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
- Medication must be prescribed by a rheumatologist; AND
- Member must have least 6 months of active disease AND have five or more joints involved; AND
- Member must have tried and failed treatment with at least two non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
- Member must have tried and failed treatment with both Enbrel and Humira.
- Dosage allowed: Body weight of patient dose (once weekly subcutaneous): 10 to less than 25 kg – 50 mg; 25 to less than 50 kg - 87.5 mg; 50 kg or more - 125 mg. Weight less than 75 kg receive 10 mg/kg intravenously based on the patient's body weight. Pediatric patients weighing 75 kg or more should be administered Orencia following the adult intravenous dosing regimen, not to exceed a maximum dose of 1000 mg. Intravenous dosing has not been studied in patients younger than 6 years of age.

○ IN:

- Documented diagnosis of moderate to severe juvenile idiopathic arthritis
- Prescribed by a rheumatologist
- Age 6 years or older
- Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
- OR yearly for members with risk factors that are requesting continuation of therapy
- Joint involvement of five (5) joints or more
- Inadequate response to three (3) or more months of treatment with a DMARD (disease- modifying anti-rheumatic drug), including one (1) or more of the following:
  - methotrexate (e.g., Rheumatrex)
  - leflunomide
- Inadequate response to 12 weeks of one or more tumor necrosis factor (TNF) antagonists: e.g. adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)

- Diagnosis of Rheumatoid Arthritis

○ OH & KY:

## Immunologic Agents: Biologic Disease Modifying Agents

- Member must be 18 years of age or older with moderate to severe active RA; AND
  - Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
  - Medication must be prescribed by a rheumatologist; AND
  - Member must have tried and failed treatment with at least two non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
  - Member must have tried and failed treatment with both Enbrel and Humira.
  - Dosage allowed: Body weight of patient (intravenous): less than 60 kg - 500 mg; 60 to 100 kg – 750 mg; more than 100 kg 1000 mg. Administer by subcutaneous injection once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.
- IN:
- Documented diagnosis of moderate to severe active rheumatoid arthritis
  - Age 18 years or older
  - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
  - OR yearly for members with risk factors that are requesting continuation of therapy
  - Prescribed by a rheumatologist.
  - Inadequate response to 12 weeks or more of treatment with at least two (2) nonbiologic DMARD (disease- modifying anti-rheumatic drug), including one (1) or more of the following:
    - 5.1 methotrexate (e.g., Rheumatrex)
    - 5.2 leflunomide
    - 5.3 sulfasalazine (Azulfidine)
  - Individual has failed to respond to at least 12 weeks trial with Tumor Necrosis Factor Inhibitors



## Immunologic Agents: Immunosuppressants – Antimetabolites

Current PDL	Recommended	Rationale	P&T Decision
<b>Preferred</b> Azathioprine (Azasan, Imuran) Mycophenolate mofetil (Cellcept) Mycophenolate sodium delayed-release (Myfortic)	None	- No new data or evidence to alter preferred agents or criteria	Approved
<b>Non-preferred</b> N/A			

## Immunologic Agents: Immunosuppressants – Calcineurin Inhibitors

Current PDL	Recommended	Rationale	P&T Decision
<b>Preferred</b> Cyclosporine (Sandimmune) capsules, solution Cyclosporine modified (Neoral) Tacrolimus (Prograf)	None	- No new data or evidence to alter preferred agents or criteria	Approved
<b>Non-preferred</b> N/A			



## Immunologic Agents: Immunosuppressants – Rapamycin Derivatives

Current PDL	Recommended	Rationale	P&T Decision
<b>Preferred</b> Everolimus (Zortress) Sirolimus (Rapamune)  <b>Non-preferred</b> Temsirolimus (Torisel) - <i>Medical benefit only</i>	None	- No new data or evidence to alter preferred agents or criteria	Approved



## Analgesics: Gout

Current PDL	Recommended	Rationale	P&T Decision
<b>Preferred</b> Allopurinol (Zyloprim) Colchicine (Colcrys) - <i>Quantity Limit: 30 tablets per month</i> Febuxostat (Uloric) - <i>Step Therapy: 30 day trial of allopurinol</i> Rasburicase (Elitek) IV solution - <i>Medical benefit only (No PA required)</i> Probenecid (Benuryl) Indomethacin (Indocin) tablets, extended-release tablets, suppository, suspension	None	- No new data or evidence to alter preferred agents or criteria	Approved
<b>Non-Preferred</b> Colchicine (Mitigare) capsule - <i>Diagnosis of gout or pericarditis with clinical reason why colchicine cannot be used after a trial.</i> Pegloticase (Krystexxa) solution - <i>Diagnosis of gout</i> - <i>Prescribed by rheumatologist</i> - <i>Trials of allopurinol and then colchicine or uloric</i> Indomethacin (Tivorbex) capsule - <i>Documentation of trial of indomethacin capsule</i> Lesinurad (Zurampic) - <i>Diagnosis of hyperuricemia with gout</i> - <i>90 day trial and failure of allopurinol or febuxostat</i> - <i>MUST be in combination with allopurinol or febuxostat (send to RPh if documentation or claims indicate it is monotherapy)</i> - <i>Quantity limit: 30 tablets per 26 days</i> Allopurinol (Aloprim) IV solution			



## Immunologic Agents: Immunomodulators

Current PDL	Recommended	Rationale	P&T Decision
<p><b>Preferred</b></p> <p>Lenalidomide (Revlimid)</p> <ul style="list-style-type: none"> <li>- Member needs one of the following: <ul style="list-style-type: none"> <li>o Diagnosis of mantle cell lymphoma AND member has failed two prior therapy including bortezomib.</li> <li>o Diagnosis of multiple myeloma following autologous stem cell transplantation used in combination with dexamethasone and has received at least 1 prior treatment.</li> <li>o Diagnosis of myelodysplastic syndromes with a deletion 5q (del 5q) cytogenic abnormality</li> </ul> </li> </ul> <p>Pomalidomide (Pomalyst)</p> <ul style="list-style-type: none"> <li>- Diagnosis of multiple myeloma</li> <li>- Prescribed by or in consultation with an oncologist</li> <li>- Failed at least 3 prior lines of therapy including a protease inhibitor and immunomodulatory agent</li> </ul> <p>Thalidomide(Thalomid)</p> <ul style="list-style-type: none"> <li>- Diagnosis of multiple myeloma or erythema nodosum leprosum</li> </ul> <p>Interferon alfa-2b (Intron-A)</p> <ul style="list-style-type: none"> <li>- Condyloma Acuminata <ul style="list-style-type: none"> <li>o Involvement of external surfaces of genital and/or perianal areas and unsatisfactory response to 1 or more of the following: <ul style="list-style-type: none"> <li>▪ Cryotherapy</li> <li>▪ Laser therapy</li> <li>▪ Podophyllin resin</li> <li>▪ Surgery</li> </ul> </li> </ul> </li> <li>- Hairy cell leukemia <ul style="list-style-type: none"> <li>o Patients who have relapsed or who have had a less than complete response to first-line therapy with a purine analogue</li> </ul> </li> <li>- Malignant Melanoma <ul style="list-style-type: none"> <li>o High risk for systemic recurrence, as indicated by 1 (one) or more of the following: <ul style="list-style-type: none"> <li>▪ Stage IIB or IIC (ie, Breslow thickness greater than 4mm)</li> <li>▪ Stage III (ie, primary or recurrent nodal involvement)</li> </ul> </li> </ul> </li> <li>- Renal Cancer <ul style="list-style-type: none"> <li>o Predominant clear cell histology</li> <li>o Relapsed or unresectable stage IV disease</li> <li>o Used concurrently with bevacizumab</li> </ul> </li> <li>- Symptomatic systemic mastocytosis <ul style="list-style-type: none"> <li>o Documented diagnosis confirmed by medical record/chart</li> </ul> </li> </ul> <p>Interferon gamma-1b (Actimmune)</p> <ul style="list-style-type: none"> <li>o Diagnosis of chronic granulomatous disease or malignant osteoporosis</li> </ul>	None	<ul style="list-style-type: none"> <li>- No new data or evidence to alter preferred agents or criteria</li> </ul>	Approved



## Immunologic Agents: Immunomodulators

### Peginterferon alfa-2a (Pegasys)

- OH & KY:
  - Chronic Hepatitis C
    - o Documented diagnosis of Hepatitis C
    - o Prescribed by a hepatologist, gastroenterologist or infectious disease specialist
    - o Negative pregnancy test for female of child bearing potential
    - o Not currently enrolled in hospice
    - o Not currently participating in alcohol abuse or illicit substance abuse:
      - One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
      - Previous abusers must meet ALL the following:
        - Enrolled for at least 6 months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
        - Confirmed current monthly negative urine drug and alcohol screen for 3 (three) consecutive months
    - o Provided detectable HCV RNA levels are higher than 50 IU/ml
    - o Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest- ActiTest panel or Fibroscan only
    - o Must be in combination with ribavirin and a DAA (Direct Acting Agent)
  - Chronic Hepatitis B
    - o Documented diagnosis of compensated chronic hepatitis B (Hep B surface antigen positive for at least 6 (six) months or Hep B viral DNA level greater than (20,000 IU/ml, 100,000 copies/ml)
    - o Prescribed by a gastroenterologist, infectious disease specialist or hepatologist
    - o Not currently participating in alcohol abuse or illicit substance abuse:
      - One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
      - Previous abusers must meet ALL the following:
        - Enrolled for at least 6 (six) months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
        - Confirmed current monthly negative urine drug and alcohol screen for 3 (three) consecutive months
    - o Not a previous non-responder
    - o Patient has compensated liver disease
- IN:
  - o Excluded benefit

## Immunologic Agents: Immunomodulators

Peginterferon alfa-2b (Sylatron)

- Diagnosis of melanoma

Rilonacept (Arcalyst)

- Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) Which Includes Familial Cold Auto-Inflammatory Syndrome (FCAS) And Muckle-Wells Syndrome (MWS) AND there is laboratory evidence of a genetic mutation In the Cold-Induced Auto-Inflammatory Syndrome 1 (CIAS1 – Sometimes Referred To As The NLRP3)

Canakinumab (Ilaris)

- OH & KY:
  - o Juvenile idiopathic arthritis or cryopyrin-associated periodic syndrome (CAPS)
    - Member must be 4 years of age or older; AND
    - Member must be diagnosed with Familial Cold Autoinflammatory Syndrome (FCAS) OR Muckle-Wells Syndrome; AND
    - Prescriber has submitted laboratory evidence of a genetic mutation in the Cold-Induced Auto-Inflammatory Syndrome 1 (CIAS1—sometimes referred to as the NLRP3); AND
    - Medication must be prescribed by a rheumatologist or under recommendation of a rheumatologist or CAPS specialist; AND
    - Must have a documented negative TB test within 6 months prior to starting therapy.
    - Dosage allowed: 150 mg for CAPS patients with body weight greater than 40 kg and 2 mg/kg for CAPS patients with body weight greater than or equal to 15 kg and less than or equal to 40 kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg. Administer subcutaneously every 8 weeks.
  - o Familial Mediterranean fever with genetic confirmation and intolerance to colchicine
    - Member's Physician's Global Assessment (PGA) Disease Activity score is  $\geq 2$  documented in chart notes with key signs and symptoms of FMF: abdominal pain, skin rash, chest pain, arthralgia/arthritis.
    - Member's C-reactive protein (CRP) > 10 mg/L is documented in chart notes; AND
    - Member has documentation of at least one flare per month.
  - o Hyperimmunoglobulin D syndrome, mevalonate kinase deficiency with confirmed DNA analysis
    - Member's Physician's Global Assessment (PGA) Disease Activity score is  $\geq 2$  documented in chart notes with key signs and symptoms of HIDS/MKD: abdominal pain; lymphadenopathy, aphthous ulcers; AND

## Immunologic Agents: Immunomodulators

- Member's C-reactive protein (CRP) > 10 mg/L is documented in chart notes; AND
- Member has documentation of  $\geq 3$  febrile acute flares within a 6 month period.
- Dosage allowed: Body weight  $\geq 40$  kg: starting dose is 2 mg/kg every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate. Body weight <40 kg: starting dose is 150 mg every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
  - Member's Physician's Global Assessment (PGA) Disease Activity score is  $\geq 2$  documented in chart notes with key signs and symptoms of TRAPS: abdominal pain, skin rash, musculoskeletal pain, eye manifestations; AND
  - Member's C-reactive protein (CRP) > 10 mg/L is documented in chart notes; AND
  - Member has documentation of at least 6 flares per year.
  - Dosage allowed: Body weight  $\geq 40$  kg: starting dose is 2 mg/kg every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate. Body weight <40 kg: starting dose is 150 mg every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.
- IN:
  - Cryopyrin-associated periodic syndromes (CAPS) which include Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) when ALL of the following are met:
    - Age 4 years or older
    - Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy
    - OR yearly for members with risk factors that are requesting continuation of therapy
    - Prescribed by a rheumatologist
    - There is clinical documentation that the patient is experiencing the classic symptoms of CAPS, defined as meeting either criterion below:
      - Familial Cold Auto-Inflammatory Syndrome (FCAS) – Recurrent intermittent episodes of fever and rash that primarily follow natural, artificial (eg, air conditioning) or both types of generalized cold exposure
      - OR

## Immunologic Agents: Immunomodulators

- *Muckle-Wells Syndrome (MWS) – Syndrome of chronic fever and rash that may wax and wane in intensity; sometimes exacerbated by generalized cold exposure. This syndrome may be associated with deafness or amyloidosis*
- *Juvenile Idiopathic Arthritis (JIA) systemic, when ALL of the following are met:*
  - *Individual is two (2) years of age or older*
  - *Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy*
  - *OR yearly for members with risk factors that are requesting continuation of therapy*
  - *Prescribed by a rheumatologist*
  - *Systemic juvenile idiopathic arthritis, as indicated by arthritis involving two (2) or more joints AND one (1) or more of the following:*
    - *Evanescant erythematous rash*
    - *Fever for at least two (2) weeks*
    - *Generalized lymphadenopathy*
    - *Hepatomegaly or splenomegaly*
    - *Pericarditis, pleuritic, or peritonitis*
    - *Inadequate response to ALL of the following:*
    - *Glucocorticosteroid injection*
    - *Methotrexate*
    - *NSAIDs after a 12-week trial*
    - *Tumor necrosis factor-alpha inhibitor (eg, adalimumab (Humira)) after a 12 -week trial*

Tocilizumab (Actemra)

- OH & KY:

- *Diagnosis of RA*
  - *Member must be 18 years of age or older with moderate to severe active RA; AND*
  - *Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND*
  - *Medication must be prescribed by a rheumatologist; AND*
  - *Member must have tried and failed treatment with at least two non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented*

## Immunologic Agents: Immunomodulators

- contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND*
- *Dosage allowed: Body weight <100 kg: 162 mg per kg administered subcutaneously every other week, followed by an increase to every week based on clinical response; body weight ≥100 kg: 8 mg per kg administered subcutaneously every week.*
- *Diagnosis of JIA*
    - *Member must be 2 years of age or older with moderate to severe active PJIA; AND*
    - *Member has documented diagnosis of active systemic juvenile idiopathic arthritis or polyarticular juvenile idiopathic arthritis; AND*
    - *Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND*
    - *Medication must be prescribed by a rheumatologist; AND*
    - *Member must have an inadequate response to methotrexate or inability to tolerate methotrexate.*
    - *Member must have least 6 months of active disease AND at least one of the following signs or symptoms:*
      - *Four or fewer joints involved with an inadequate response to glucocorticosteroid injection AND methotrexate AND NSAID treatment for at least 12 weeks;*
      - *Five or more joints involved AND an inadequate response to methotrexate.*
    - *Dosage allowed:*
      - *For polyarticular JIA: body weight <30 kg: 10 mg per kg; body weight ≥30 kg: 8 mg per kg.*
      - *For systemic JIA: Body weight <30 kg: 12 mg per kg; body weight ≥30 kg: 8 mg per kg.*
- IN:
- *Rheumatoid Arthritis when ALL of the following are met:*
    - *Documented diagnosis of moderate to severe active rheumatoid arthritis*
    - *Age 18 years or older*
    - *Prescribed by a rheumatologist*
    - *Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release*
    - *assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy*



## Immunologic Agents: Immunomodulators

- *OR yearly for members with risk factors that are requesting continuation of therapy*
- *Individual has failed to respond to at least 12 weeks of two (2) non-biologic DMARDs*
- *Juvenile Idiopathic Arthritis when ALL of the following are met:*
  - *Documented diagnosis of active systemic juvenile idiopathic arthritis or polyarticular juvenile idiopathic arthritis*
  - *Age 2 years or older*
  - *Documented negative TB test (ie, tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to initiating a biologic therapy*
  - *OR yearly for members with risk factors that are requesting continuation of therapy*
  - *Prescribed by a rheumatologist*
  - *Inadequate response to treatment with tumor necrosis factor-alpha inhibitor AND disease-modifying anti-rheumatic drug after 12-week trial*
  - *Joint involvement and treatment scenario includes one (1) or more of the following:*
  - *Four or fewer joints involved and inadequate response to ALL of the following:*
    - *Glucocorticosteroid injection*
    - *Methotrexate*
    - *NSAIDs after a 12-week trial*
    - *Five or more joints involved and inadequate response to methotrexate*

Non-Preferred

**N/A**



## Analgesics: Narcotics

Current PDL	Recommended	Rationale	P&T Decision
<b>Preferred</b> Butalbital/acetaminophen/cafeine/codeine (Fioricet with codeine) - Quantity limit: 48 capsules per 26 days Butalbital/aspirin/cafeine/codeine (Fiorinal with codeine) - Quantity limit: 48 capsules per 26 days Butorphanol (Stadol) spray - Quantity limit: 2 bottles per month Codeine/acetaminophen (Tylenol with codeine) - Quantity limit: 300 tablets per 26 days Fentanyl citrate buccal (Fentora) - Diagnosis of breakthrough pain in adults with cancer with tolerant opioid therapy or clinical criteria Fentanyl lozenge (Actiq) - Diagnosis of breakthrough pain in adults with cancer with tolerant opioid therapy or clinical criteria Fentanyl sublingual (Abstral) - Diagnosis of breakthrough pain in adults with cancer with tolerant opioid therapy or clinical criteria Fentanyl transdermal (Duragesic) - Quantity limit: 10 patches per month - Member must be 18 years old - Diagnosis of cancer related pain, sickle cell disease, terminally ill, or hospice - OR - Diagnosis of chronic non-cancer related pain AND all of the following: <ul style="list-style-type: none"> <li>o Prescribed by pain management specialist</li> <li>o At least 30 day trials of other preferred immediate release agents</li> <li>o Documented inadequate response to IR opioid therapy with use of IR opioid therapy supported by pharmacy claims</li> <li>o No claims for buprenorphine, naloxone, or naltrexone products in past 12 months</li> </ul> Fentanyl citrate injection (Sublimaze) - Medical benefit only Hydrocodone/acetaminophen (Norco, Lorcet, Lortab, Vicodin ES, Vicodin HP) tablet, (Hycet) solution - Quantity limits: <ul style="list-style-type: none"> <li>o 2.5-325mg, 5-325mg, 7.5-325mg, 10-325mg -- 300 tablets per month</li> <li>o 5-500mg -- 210 tabs per month</li> <li>o 7.5-500mg, 10-500mg -- 180 tabs per month</li> <li>o 7.5-650mg, 10-650mg -- 120 tabs per month</li> <li>o 10-660mg -- 150 tabs per month</li> <li>o 7.5-750mg -- 150 tabs per month</li> <li>o 7.5-325mg/15mL -- 3750 mL per month</li> </ul> Hydrocodone/ibuprofen (Vicoprofen)	<ul style="list-style-type: none"> <li>- Remove Avinza</li> <li>- Add Butorphanol Spray to Ohio and Kentucky PDL</li> <li>- Remove strengths of hydrocodone/acetaminophen with &gt; 325 mg acetaminophen</li> <li>- Remove Panlor as a trial agent for Synalgos-DC and add acetaminophen-codeine as a trial agent</li> </ul>	<ul style="list-style-type: none"> <li>- Avinza discontinued</li> <li>- OH &amp; KY PDL: Update butorphanol for consistency with UFF.</li> <li>- Hydrocodone/acetaminophen containing &gt; 325 mg of acetaminophen have been discontinued</li> <li>- Panlor no longer available</li> </ul>	Approved



## Analgesics: Narcotics

<ul style="list-style-type: none"> <li>- <i>Quantity limit: 150 tablets per month</i></li> </ul> <p>Hydromorphone (Dilaudid) tablets, solution</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit:</i> <ul style="list-style-type: none"> <li>o <i>180 tablets per month</i></li> <li>o <i>180 mL per month</i></li> </ul> </li> </ul> <p>Meperidine (Demerol) tablets, solution</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit:</i> <ul style="list-style-type: none"> <li>o <i>12 tablets per month</i></li> <li>o <i>30 mL per month</i></li> </ul> </li> </ul> <p>Methadone (Dolophine) tablets, solution</p> <ul style="list-style-type: none"> <li>- <i>OH &amp; KY:</i> <ul style="list-style-type: none"> <li>o <i>Quantity limits:</i> <ul style="list-style-type: none"> <li>• <i>5 mg – 120 tablets per month</i></li> <li>• <i>10mg – 60 tablets per month</i></li> <li>• <i>10mg/mL – 30 mL per month</i></li> <li>• <i>5 mg/5mL – 600 mL per month</i></li> <li>• <i>10 mg/5mL – 300 mL per month</i></li> </ul> </li> <li>o <i>Member must be 18 years old</i></li> <li>o <i>Diagnosis of cancer related pain, sickle cell disease, terminally ill, or hospice</i></li> <li>o <i>OR</i></li> <li>o <i>Diagnosis of chronic non-cancer related pain AND all of the following:</i></li> <li>o <i>Prescribed by pain management specialist</i></li> <li>o <i>At least 30 day trials of other preferred immediate release agents</i></li> <li>o <i>Documented inadequate response to IR opioid therapy with use of IR opioid therapy supported by pharmacy claims</i></li> <li>o <i>No claims for buprenorphine, naloxone, or naltrexone products in past 12 months</i></li> </ul> </li> <li>- <i>IN:</i> <ul style="list-style-type: none"> <li>o <i>Quantity limits:</i> <ul style="list-style-type: none"> <li>• <i>5 mg – 240 tablets per month</i></li> <li>• <i>10mg – 60 tablets per month</i></li> <li>• <i>10mg/mL – 30 mL per month</i></li> <li>• <i>5 mg/5mL – 600 mL per month</i></li> <li>• <i>10 mg/5mL – 300 mL per month</i></li> </ul> </li> <li>o <i>Member must be 18 years old</i></li> <li>o <i>Diagnosis of cancer related pain, sickle cell disease, terminally ill, or hospice</i></li> <li>o <i>OR</i></li> <li>o <i>Diagnosis of chronic non-cancer related pain AND all of the following:</i></li> <li>o <i>Prescribed by pain management specialist</i></li> </ul> </li> </ul>			
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## Analgesics: Narcotics

<ul style="list-style-type: none"> <li>○ <i>At least 30 day trials of other preferred immediate release agents</i></li> <li>○ <i>Documented inadequate response to IR opioid therapy with use of IR opioid therapy supported by pharmacy claims</i></li> <li>○ <i>No claims for buprenorphine, naloxone, or naltrexone products in past 12 months</i></li> </ul> <p>Morphine sulfate immediate release tablets, solution, suppository</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit:</i> <ul style="list-style-type: none"> <li>○ <i>180 tabs per month</i></li> <li>○ <i>900mL per month</i></li> <li>○ <i>180 suppositories per month</i></li> </ul> </li> </ul> <p>Morphine tablets, (MS Contin) extended-release tablets, solution</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit:</i> <ul style="list-style-type: none"> <li>○ <i>20mg/mL – 180 mL per month</i></li> <li>○ <i>15mg, 30mg, 60mg – 120 extended-release tablets per month</i></li> <li>○ <i>100mg, 200mg – 60 extended-release tablets per month</i></li> </ul> </li> <li>- <i>Member must be 18 years old</i></li> <li>- <i>Diagnosis of cancer related pain, sickle cell disease, terminally ill, or hospice</i></li> <li>- <i>OR</i></li> <li>- <i>Diagnosis of chronic non-cancer related pain AND all of the following:</i> <ul style="list-style-type: none"> <li>○ <i>Prescribed by pain management specialist</i></li> <li>○ <i>At least 30 day trials of other preferred immediate release agents</i></li> <li>○ <i>Documented inadequate response to IR opioid therapy with use of IR opioid therapy supported by pharmacy claims</i></li> <li>○ <i>No claims for buprenorphine, naloxone, or naltrexone products in past 12 months</i></li> </ul> </li> </ul> <p>Morphine extended-release (Kadian) capsules</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit:</i> <ul style="list-style-type: none"> <li>○ <i>10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 80mg – 60 capsules per month</i></li> <li>○ <i>100mg, 200mg – 30 capsules per month</i></li> </ul> </li> <li>- <i>Member must be 18 years old</i></li> <li>- <i>Diagnosis of cancer related pain, sickle cell disease, terminally ill, or hospice</i></li> <li>- <i>OR</i></li> <li>- <i>Diagnosis of chronic non-cancer related pain AND all of the following:</i> <ul style="list-style-type: none"> <li>○ <i>Prescribed by pain management specialist</i></li> <li>○ <i>At least 30 day trials of other preferred immediate release agents</i></li> <li>○ <i>Documented inadequate response to IR opioid therapy with use of IR opioid therapy supported by pharmacy claims</i></li> <li>○ <i>No claims for buprenorphine, naloxone, or naltrexone products in past 12 months</i></li> </ul> </li> </ul> <p>Oxycodone (Roxicodone) tablets, capsules, concentrate, solution</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit:</i> <ul style="list-style-type: none"> <li>○ <i>180 tablets or capsules per month</i></li> </ul> </li> </ul>			
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## Analgesics: Narcotics

- 20mg/mL – 180 mL per month
- 5mg/mL – 180 mL per month
- Oxycodone extended-release (Oxycontin)
  - *Quantity limit: 60 tablets per month*
  - *Diagnosis of pain with a 30 day trial of fentanyl patches, morphine sulfate ER, or oxymorphone ER (all require a PA)*
  - *May approve if patient is age 11-18 years old with diagnosis of cancer, trauma, or major surgery*
- Oxycodone/acetaminophen (Percocet, Endocet) tablets, solution
  - *Quantity limit:*
    - 300 tablets per month
    - 1385 mL per month
- Oxycodone/aspirin (Percodan)
  - *Quantity limit:*
    - 308 tablets per month
- Oxymorphone extended-release (Opana ER)
  - *Quantity limit:*
    - 5mg, 7.5mg, 10mg, 15mg, 20mg – 120 tablets per month
    - 30mg, 40mg – 60 tablets per month
  - *Clinical reason supported by chart notes why after trial of oxymorphone SR (Opana ER) non-crush resistant product, it cannot be used AND prescriber feels there is potential for abuse*
- Tramadol (Ultram)
  - *Quantity limit:*
    - 240 tablets per month
- Tramadol/acetaminophen (Ultracet)
  - *Quantity limit:*
    - 40 tablets per month

### Non-Preferred

- Butalbital/acetaminophen/caffeine (Vanadol) solution
  - *Quantity limit: 720mL per month*
  - *Clinical reason why (after trial of) butalbital/acetaminophen/caffeine tablets cannot be used*
- Carisoprodol/aspirin/codeine tablet
  - *Step therapy: 30 day trial of carisoprodol 350mg tabs*
- Dihydrocodeine/aspirin/caffeine capsules (Synalgos)
  - *30 day trial of Panlor/Panlor SS*
- Fentanyl (Duragesic) 37.5mcg/hr, 62.5mcg/hr, 87.5mcg/hr patch
  - *Quantity limit: 10 patches per 30 days*
  - *Clinical reason after 30 day trial of formulary strength patches*
- Fentanyl (Lazanda) nasal spray

## Analgesics: Narcotics

<ul style="list-style-type: none"> <li>- <i>Diagnosis of breakthrough pain in cancer who are tolerant to opioid therapy</i></li> <li>- <i>Clinical reason after 30 day trial of fentanyl lozenge (Actiq)</i></li> </ul> <p>Fentanyl (Subsys) sublingual liquid</p> <ul style="list-style-type: none"> <li>- <i>Diagnosis of breakthrough pain in adults with cancer who are receiving and are tolerant to opioid therapy</i></li> </ul> <p>Hydrocodone/acetaminophen (Zamiset) solution</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 3,750mL per month</i></li> <li>- <i>At least a 30 day trial of hydrocodone/acetaminophen (Lortab) 7.5-500mg/15mL solution</i></li> </ul> <p>Hydrocodone/acetaminophen (Xodol) tablets</p> <ul style="list-style-type: none"> <li>- <i>Clinical reason why (after trial of) hydrocodone/acetaminophen 5-325mg cannot be used</i></li> </ul> <p>Hydrocodone/ibuprofen (Reprexain) tablets</p> <ul style="list-style-type: none"> <li>- <i>Clinical reason why (after trial of) hydrocodone/ibuprofen (Vicoprofen) cannot be used.</i></li> </ul> <p>Hydrocodone (Hysingla) extended-release abuse-deterrent tablet</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 30 tablets per month</i></li> <li>- <i>Required 30 day trial of fentanyl patches, morphine sulfate ER (MS Contin), or oxymorphone ER</i></li> <li>- <i>Provider must feel there is potential for abuse</i></li> </ul> <p>Hydrocodone (Zohydro) extended-release abuse-deterrent capsules</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 60 tablets per month</i></li> <li>- <i>Required 30 day trial of fentanyl patches, morphine sulfate ER (MS Contin), or oxymorphone ER</i></li> </ul> <p>Hydromorphone (Exalgo) extended-release abuse-deterrent tablet</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 30 capsules per month</i></li> <li>- <i>Required 30 day trial of fentanyl patches, morphine sulfate ER (MS Contin), or oxymorphone ER</i></li> </ul> <p>Levorphanol tablet</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 180 tablets in 30 days</i></li> <li>- <i>Clinical reason why preferred product cannot be used or 30 day trial of morphine sulfate IR</i></li> </ul> <p>Morphine sulfate extended-release beads capsule (Avinza)</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit</i> <ul style="list-style-type: none"> <li>o <i>30mg, 45mg, 60mg – 60 capsules in 30 days</i></li> <li>o <i>75mg, 90mg, 120mg – 30 capsules in 30 days</i></li> </ul> </li> <li>- <i>Clinical reason after trial of morphine sulfate ER</i></li> </ul> <p>Oxycodone/Acetaminophen (Primlev) 5-300, 10-300, 7.5-300 tablets</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 300 tablet per month</i></li> <li>- <i>Clinical reason (after trial of) Oxycodone/acetaminophen 10/325cannot be used</i></li> </ul> <p>Oxycodone/Acetaminophen (Xartemis XR) tablet</p> <ul style="list-style-type: none"> <li>- <i>Clinical reason (after trial of) Oxycodone/acetaminophen 10/325 cannot be used</i></li> </ul> <p>Oxycodone (Xtampza) 12-hour extended release abuse deterrent capsule</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 60 capsules per month</i></li> <li>- <i>Diagnosis of severe pain requiring around the clock, long-term opioid treatment.</i></li> </ul>			
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## Analgesics: Narcotics

<ul style="list-style-type: none"> <li>- <i>Clinical reason supported by chart notes why oxycodone ER (Oxycontin) cannot be used (after 30 day trial of agent) AND provider feels there is potential for abuse</i></li> </ul> <p>Oxycodone (Oxaydo) abuse-deterrent tablet</p> <ul style="list-style-type: none"> <li>- <i>Clinical reason why oxycodone IR tablet cannot be used (after trial of agent)</i></li> </ul> <p>Oxycodone-ibuprofen tablet</p> <ul style="list-style-type: none"> <li>- <i>30 day trial of oxycodone/acetaminophen or fentanyl</i></li> </ul> <p>Oxymorphone (Opana) immediate release tablet</p> <ul style="list-style-type: none"> <li>- <i>30 day trial of morphine sulfate IR</i></li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>- <i>Current paid claims for oxymorphone SR (Opana ER) for 60 days within the past 120 days</i></li> </ul> <p>Tapentadol (Nucynta) tablet, extended-release tablet</p> <ul style="list-style-type: none"> <li>- <i>Quantity limit: 60 tablets in 27 days</i></li> <li>- <i>Clinical reasoning or at least a 30 day trial of immediate release morphine, oxycodone, oxycodone-acetaminophen</i></li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>- <i>Clinical reason or 30 day trial of morphine sulfate ER, oxymorphone ER, or fentanyl patches</i></li> </ul> <p>Tramadol (Conzip) ER capsule</p> <ul style="list-style-type: none"> <li>- <i>Clinical reason after 30 day trial of tramadol IR then tramadol ER tab (requires PA)</i></li> </ul> <p>Acetaminophen/caffeine/dihydrocodeine (Trezix)</p> <p>Morphine sulfate (MorphoBond) 12-hour extended release abuse deterrent tablet</p> <p>Morphine sulfate (Arymo) extended release tablet</p> <p>Synalgos-DC (Aspirin/caffeine/dihydrocodeine capsule)</p> <ul style="list-style-type: none"> <li>- <i>30 day Trial of: ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE (PANLOR/PANLOR SS)</i></li> </ul> <p>712.8-60-32MG TABLET</p>			
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