

MSI Prior Authorization Criteria

Rev. 8/18/2009

Anemia Agent (Epoetin)

PA Criteria based on CMS National Coverage Decision

- Administration
 1. Initiation Period (first 4 weeks)
 - a. Hb level < 10 g/dL
weeks
 - c. Darbepoetin – 2.25mcg/kg/week or 500 mcg q3weeks
 2. Maintenance Period (beyond 4 weeks)
 - a. Hb level < 10g/dL
 - b. May continue for 8 weeks following completion of final CTX dose
- Dose Adjustment
 1. Hb rise < 1 g/dL in 4 weeks and Hb < 10 g/dL – increase dose by 25%
 2. Hb rise > 1 g/dL in any 2 consecutive weeks – decrease dose by 25% if Hb < 10 g/dL
- Responder
 1. ≥ 1 g/dL -- increase within 8 weeks of initiation

NOTES:

- ✓ For reference –
 - o [CMS Medicare criteria – http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=203](http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=203)
 - o ASH/ASCO 2007 clinical practice guidelines (J Clin Oncol, Vol. 25, 34, December 2007).
 - o There are conflicts between CMS and ASH/ASCO guidelines,

guidelines state “—based on comprehensive systematic review comparing outcomes of ESAs in patients with chemotherapy-induced anemia, and on identical cancer-related indications, warnings, and cautions in the relevant FDA-approved PI, these agents are considered to be equivalent with respect to effectiveness and safety.” [Note that while the comment applies to cancer only, comparisons of the two drugs do not indicate a benefit of Darbepoetin over Epoetin in general.]

Antidiabetic Medications – Prior Authorization / Step Therapy Criteria

Step Therapy:

- Step 1 – Metformin
- Step 2 – Sulfonylurea
- Step 3 – TZD or Insulin
 - TZD requires PA – PA Criteria: Provider must provide the following:
 - following
the use of TZDs**
 - 2. No evidence of CHF or bone fractures**
 - 3. Recent result of hemoglobin A1c – A1c must be \leq 8.5%**
 - 4. Both #1 and 2 criteria must be met for approval. All other requests will be denied**
 - 5. If TZDs are denied, then Insulin (see formulary for approved insulins) is the only approved Step 3 therapy.**
 - Nurses can approve Prior Authorizations for up to 12 months

OPTIONS FOR BRANDED PRESCRIBING:

1. Apply to PAP program -- MSI is NOT an insurance so inform the patients that they are not covered on any insu
2. Apply to Partnership for Prescription Assistance
3. Switch Brand drugs/categories to the Formulary alternatives.
4. Refer patients to pharmacies that offer generics at a discount, e.g., \$4 for 30 days.

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For reference the ADA guidelines are:

- ADA Guidelines:
 - Diabetes Care, Volume 30, Supplement 1, January 2007
 - Diabetes Care 29:1963-1972, No. 8, August 2006
- Insulin Management Recommendations:
 - Diabetes Care 29:1963-1972, 2006
 - Ann Intern Med 145:125-134, 2006
- Nutrition Recommendations:
 - Diabetes Care 29:2140-2157, 2006
 - New ADA consensus statement expected in 2007

For the subset of patients for whom there is no functional pancreas and maximal doses of sulfonylureas have been tried, an expedited review for TZDs is possible under the following criteria:

- Failed a trial (minimum of a three month period) of a sulfonylurea at maximum doses. Physician must confirm.
 - Patient is on metformin.
- TZD requires PA – PA Criteria: Provider must provide the following (same as 1-3 in TZD PA criteria at
1. **Statement that patient has no cardiovascular risk factors, including CAD and CHF**
 2. **Recent result of hemoglobin A1c – A1c must be \leq 8.5%**
 3. **Both #1 and 2 criteria must be met for approval. All other requests will be denied.**
 4. **Nurses can approve Prior Authorizations for up to 12 months**

Antiemetics

Recommend Ondansetron (Zofran generic) x 3 days / course of therapy

PA Criteria

1. Patient must have documentation of FDA approved diagnosis
2. Ondansetron ODT (oral disintegrating tablet) will NOT be approved due to lack of objective, clinical, therapeutic, and kinetic rationale that demonstrates superiority over the tablet formulation

FDA Approved diagnoses:

- Nausea and vomiting secondary to chemotherapy (8-24mg/day of chemotherapy) ---- 8mg daily, BID or TID
- Post-operative nausea and vomiting surgery= 16mg prior anesthesia
- Radiation therapy (MSI specific clinical addition) radiation = 8mg daily to TID

Non-FDA Approved indications (Not approvable by MSI)

- Alcoholism up to 2mg BID for 6 weeks
- Hyperemesis gravidarum in children
- Pruritus 4mg BID up to 5 mo

Antihypertensives: (For reference only.)

Step Therapy for uncomplicated HTN:

- Step 1 – Thiazide Diuretics
- Step 2 – ACE Inhibitor, Calcium Channel Blocker, and/or Beta Blocker
- Step 3 – ARB (only after Thiazides, ACEI, CCB, and BB titrated to maximum tolerable and effective

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Protocol for patients with HTN + Diabetes Mellitus, Congestive Heart Failure, or Chronic Kidney Disease

- Step 1 – Thiazide Diuretics
- Step 2 – ACE Inhibitor, Calcium Channel Blocker, and/or Beta Blocker
- Step 3 – ARB
 - ARB requires PA – PA Criteria: Provider must provide the following criteria:
 1. **Documentation that an ACE, CCB, and BB have been tried and patient has not reached BP goals -- OR**
 2. **Intractable and unrelenting cough daily for > 2 weeks while on ACEI -- OR and has tried ACEI**
 - **If patient has CKD, there must be documentation of GFR and stage level of > 2 Cl**
 - Stage 1** with normal or high GFR (GFR > 90 ml/min)
 - Stage 2** Mild CKD (GFR = 60-89 ml/min)
 - Stage 3** Moderate CKD (GFR = 30-59 ml/min)
 - Stage 4** Severe CKD (GFR = 15-29 ml/min)
 - Stage 5** End Stage CKD (GFR <15 ml/min)
 - **#1 or 2 criteria must be met for approval. All other requests will be denied.**
- Nurses can approve Prior Authorizations for up to 12 months

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1. Apply to PAP program -- MSI is NOT an insurance so inform the patients that they are not covered on any insurance
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4. Refer patients to pharmacies that offer generics at a discount, e.g., \$4 for 30 days.

Bisphosphonates: Alendronate generic is preferred choice; Risedronate (Actonel™) brand is non-formulary

Indications (FDA approved)

- Osteoporosis
- Osteoporosis prophylaxis
- Paget's disease

Non-FDA approved

- Osteolytic metastases

PA Criteria

1. Bone studies may be performed on different anatomic sites -- DXA scans of the hip are the standard measurement for osteoporosis (CPT Codes for relevant studies are 77078 – 77082)
2. Bone mineral density: T score \leq -2.5
 - a. High risk patients: menopausal women with family history of fractures, Caucasian, Asian race and early menopause. In Paget's disease with alkaline 2x the normal range or symptomatic patients who are at risk for future complications.
3. Patients with BMD T score \leq -1.5 if additional risks present
 - a. Previous fracture as an adult
 - b. History of fragility fracture in a first degree relative
 - c. Body weight <57kg
 - d. Current smoking
 - e. Use of oral steroid therapy for >3months
 - f. Previous vertebral, Hip or wrist fracture
4. Postmenopausal women who have had an osteoporotic vertebral fracture; who have bone mineral density values consistent with osteoporosis (ie, T-score worse than or equal to -2.5); OR who have a T-score from -2.0 to -2.5 plus at least one of the following risk factors for fracture: thinness, history of fragility fracture (other than skull, facial bone, ankle, finger, and toe) since menopause, and history of hip fracture in a parent.

OPTIONS FOR BRANDED PRESCRIBING:

1. Apply to PAP program -- MSI is NOT an insurance so inform the patients that they are not covered on any insurance
2. Apply to Partnership for Prescription Assistance
3. Switch Brand drugs/categories to the Formulary alternatives.
4. Refer patients to pharmacies that offer generics at a discount, e.g., \$4 for 30 days.

NOTES:

- Regular exercise, adequate diet, discontinue smoking and preventative measures in home so that falls are avoided. Vitamin D & Calcium recommended.

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Clonazepam – Prior Authorization / Step Therapy Criteria

PA criteria. Physician must provide the following:

1. Indication of the type of seizure the patient is experiencing
2. Documented evidence of the seizure
3. Both #1 and #2 criteria must be met for approval. All other requests will be denied
4. Depending on the type of seizure, step therapy guidelines must be followed.
5. Nurses can approve Prior Authorizations for up to 12 months systematically studied in controlled clinical trials. The physician who elects to use Clonazepam for extended periods should

Clonazepam is FDA approved for the following types of seizures:

- Atonic Seizure
- Myoclonic Seizure
- Absence Seizure
- Petit mal variant seizure (Lennox-Gastaut)

Clonazepam is **NOT** FDA approved for the following types of seizures:

- Partial seizures (simple and complex)
- Tonic-Clonic Seizure (Grand mal)
- Status Epilepticus

Step Therapy for FDA approved indications:

- Step 1 - Valproic acid, divalproex, or lamotrigine use with an ADEQUATE TRIAL (defined below)
- Step 2 - Clonazepam

➤An **ADEQUATE TRIAL** of an antiepileptic drug consists of a systematic increase in the dosage and plasma drug levels until the seizures are controlled or the adverse effects become intolerable. The adequacy of the trial is not defined by time but by the frequency of seizures; the more frequent the seizures, the less time is required for determining the efficacy of a drug.

combination. The patient must be well informed about the treatment plan and, in particular, the potential adverse effects of the medication.

OPTIONS FOR ANXIETY PRESCRIBING:

1. Apply to PAP program -- MSI is NOT an insurance so inform the patients that they are not covered on any insu
2. Apply to Partnership for Prescription Assistance
3. Refer patients to pharmacies that offer generics at a discount, e.g., \$4 for 30 days.

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Hydrocodone/APAP

Indications (FDA Approved)

- Moderate pain

Non-FDA approved

- Arthralgia
- Bone pain
- Dental pain
- Headache
- Migraine
- Myalgia

PA Criteria

1. To be used in stepwise fashion starting with non-opioid analgesic
2. Caution for dosing no greater than 4Gm/day of APAP
3. Not for mild pain
4. Use only for moderate pain
5. Caution and Contraindicated in patients hypersensitive to opioids, or
 - a. Respiratory depression,
 - b. CO₂ retention,
 - d. Acute bronchial asthma,
 - d. Paralytic ileus
 - e. Head injury
 - f. Hypotension
 - g. Sleep deprivation.

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Neuropathic Pain (For reference only as all steps are not included in the MSI formulary.)

I. First Line Therapy:

- ❖ **Step 1 Acetaminophen, Aspirin, NSAIDs**
- ❖ **Step 2 NSAIDs/APAP/ASA + Opioid (hydrocodone bitartrate, oxycodone)**
- ❖ **Step 3 Moderate-Severe Pain:** See notes below.
- ❖ **Step 4 Tramadol:** Only if adequate trials of Steps 1-3 ineffective
- ❖ **Step 5 Tricyclic Antidepressants (Amitriptyline) REQUIRES PA:**

PA Criteria

1. To be used only if adequate trials of Steps 1-4 are ineffective
2. Follow titration protocol below

Tricyclic antidepressant Dosage:

- Effective doses lower than antidepressant doses
 - Initial: 10-25 mg every night
 - Titration: Every 7 days by 10-25mg/day
 - Max: 75-150mg/day OR as tolerated
3. Use only for neuropathic pain
 4. Monitor side effects closely
 5. NOT for depression

OPTIONS FOR DEPRESSION PRESCRIBING:

1. Apply to PAP program -- MSI is NOT an insurance so inform the patients that they are not covered on any insurance
2. Apply to Partnership for Prescription Assistance
3. Refer patients to pharmacies that offer generics at a discount, e.g., \$4 for 30 days.

ii. Second-Line Therapy: Only if adequate trial of First-Line treatments Steps 1-4 ineffective

- ❖ **Step 1 Gabapentin**
- ❖ **Step 2 Carbamazepine**
- ❖ **Step 3 Lamotrigine**

Duloxetine): Use

only if adequate trial of TCA ineffective (First-Line Step 5) and additional treatment with antidepressant is

III. Third-Line therapy:

- ❖ **Step 1 Lidoderm Patch (Lidocaine 5%)**

First-Line

treatments Steps 1-5 AND Second-Line Steps 1-4 ineffective

NOTES for neuropathic pain guidelines:

PA Criteria for Opioid Use:

- Schedule 2 controlled drug: requires PA
- Restricted to use only after adequate trial of Step 1 OR if diagnosis of moderate-severe pain
- Adequate trial of short-acting opioid analgesics (1-2 weeks) before use of controlled release
- Not for as needed use
- Caution and Contraindicated in Patients that are hypersensitive to opioids

PA Criteria for Opioid Use in Moderate to Severe Pain:

- **FDA-Labeled Indication: Chronic pain (Moderate to Severe)**
 - Increase dose indicated if pain reduced but no improvement of function
 - Use of more potent opioid (hydromorphone, fentanyl, methadone, morphine)
 - Limited use of short-acting opioids only for appropriate control of breakthrough pain

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References:

Nov. 2003.

Vol. 60(11). Pp 1524-1534

2. http://www.guideline.gov/summary/summary.aspx?doc_id=4671

PHYSICIANS

EDUCATION GRAM© 12/4/2006.

4. Micromedex-DrugDex Evaluations:Amitriptyline Assessed 3/19/2008.

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Oncology Medications

All oncology medications must meet the following criteria:

1. The medication(s) are FDA approved.
2. The medication(s) are being used for FDA approved indications.

Cancer Network (NCCN) compendium, "Clinical Practice Guidelines in Oncology". If the NCCN compendium lists the drug with a recommendation level 1, 2A or 2B for the condition, the service is eligible for reimbursement.

NCCN Categories of Evidence and Consensus:

Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the panel has reached uniform consensus that the recommendation is indicated.

Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate.

Category 2B: The recommendation is based on lower level evidence, and there is non-uniform consensus that the recommendation should be made.

members.

below:

http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

Oxycodone ER = OxyContin

Indications (FDA approved)

- Moderate pain
- Severe pain

Non-FDA approved

- Arthralgia
- Bone pain
- Dental pain
- Diabetic neuropathy
- Headache
- Migraine
- Myalgia
- Neuropathic pain
- Postherpetic neuralgia

PA Criteria:

1. A Schedule ii controlled medication, therefore needs prior authorization
2. Not for use on PRN basis.
3. To be used in stepwise fashion starting with non-opioid analgesic, short-acting opioid, and then extended release opioid.
4. Not for use in the first 12 to 24 hours of surgery
5. Not for mild pain
6. Use only for moderate to severe pain if persists for an extended time
7. Caution and CI in patients hypersensitive to opioids,
 - a. Respiratory depression,
 - b. CO₂ retention,
 - c. Acute bronchial asthma,

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- d. Paralytic ileus
- e. Head injury
- f. Hypotension
- g. Sleep deprivation.