### **Anemia Agent (Epoetin)**

Top of Page

### 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 g3weeks
- 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)
- o ASH/ASCO 2007 clinical practice guidelines (J Clin Oncol, Vol. 25, 34, December 2007).
- 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 Epoeitin in general.]

# <u> Antidiabetic Medications – Prior Authorization / Step Therapy Criteria</u>

Top of Page

#### 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 ≤ 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 or
- 2. Apply to Partnership for Prescription Assitance
- 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.

For	reference	the	ADA	guidelines	are:
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- 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 a
  - 1. Statement that patient has no cardiovascular risk factors, including CAD and CHF
  - 2. Recent result of hemoglobin A1c A1c must be =< 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**

Top of Page

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 rational 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.)**

Top of Page

Step Therapy for uncomplicated HTN:

Step 1 – Thiazide Diuretics

- ➤ Step 2 ACE Inhibitor, Calcium Channel Blocker, and/or Beta Blocker
- ➤ Step 3 ARB by PA for Losartan or Losartan/HCTZ only (only after Thiazides, ACEI, CCB, and BB titrated to maximum tolerable and effective dosages.)

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 (Losartan or Losartan/ HCTZ- Generics for Cozaar and Hyzaar)
  - ➤ 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 CF

      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

#### **OPTIONS FOR BRANDED PRESCRIBING:**

- 1. Apply to PAP program -- MSI is NOT an insurance so inform the patients that they are not covered or
- 2. Apply to Partnership for Prescription Assitance
- 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.

## <u>Alendronate</u> generic is preferred choice; <u>Risedronate</u> (<u>Actonel™</u>) <u>brand</u> <u>i</u>s nonformulary

Top of Page

### 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 ≤ -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 ≤ -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 or
- 2. Apply to Partnership for Prescription Assitance
- 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.

### Clonazepam - Prior Authorization / Step Therapy Criteria

Top of Page

**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.

➤ It is advisable to begin treatment with a single drug before resorting, if necessary, to two or more drugs in 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 or
- 2. Apply to Partnership for Prescription Assitance
- 3. Refer patients to pharmacies that offer generics at a discount, e.g., \$4 for 30 days.

### **EXJADE**

Top of Page

FDA approvals: transfusion iron overload (i.e., transfusion of approximately 100 ml/kg of packed red blood cel Request:

- Serum iron
- > Ferritin

- > For dosing:
  - LFTs (Liver function tests)
  - o Creatinine/BUN
  - o Urine analysis / urine osmolality

Max dose = 40 mg/kg/day

### **Hydrocodone/APAP**

Top of Page

#### 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

### Indications (FDA Approved)

Moderate pain

### Non-FDA approved

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

### Mupirocin (Bactroban) 2% Nasal Ointment

Top of Page

#### PA Criteria:

- FDA Indication: Eradication of nasal colonization with methicillin-resistant S. aureus
  - 1. (+) nasal culture for MRSA
    - FDA Recommendation: Apply in each nostril bid for 5 days
    - Bactroban Nasal is NOT FDA Indicated for:
      - ☐ Prevention of postoperative nosocomial Staphylococcus aureus infections
      - ☐ General prophylaxis of any infection in any patient population
      - ☐ Application on other parts of the body

#### Mupirocin (Bactroban) 2% Nasal Ointment Use Considerations

- 1. Has the patient's nasal culture been collected and confirmed for positive MRSA colonization in the
- 2. Does the patient have an allergy to mupirocin or any of its constituents such as paraffin?
- 3. Is the patient using any concurrent intranasal medications?
- 4. Is the patient a part of a comprehensive infection control program to reduce the risk of MRSA infe

#### \*\*\*Note\*\*\*

1. Until further information is known, bactroban intranasal should not be applied with concurrently with other intranasal products.

### formulary.)

See separate step therapies for Gabpentin (Neuropathic Pain or Anticonvulsant).

Top of Page

### I. First Line Therapy:

- ❖ Step 1 Acetaminophen, Aspirin, NSAIDs
- Step 2 NSAIDs/APAP/ASA + Opioid (hydrocodone bitartrate, oxycodone)
- ❖ Step 3 Moderate-Severe Pain: See Note for PA criteria for opioid use in moderate to severe pain
- ❖ Step 4 Tramadol: Only if adequate trials of Steps 1-3 ineffective
- **❖** Step 5 Tricyclic Antidepressants (Amitriptyline) REQUIRES PA:
  - 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 o
- 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 6 Gabapentin
  - Step 7 Carbamazepine
  - Step 8 Lamotrigine

**Duloxetine): Use** 

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

desired

- **III.** Third-Line therapy:
  - Step 10 Lidoderm Patch (Lidocaine 5%)

First-Line

treatments Steps 1-5 AND Second-Line Steps 6-8 ineffective

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.

➤ It is advisable to begin treatment with a single drug before resorting, if necessary, to two or more drugs in combination. The patient must be well informed about the treatment plan and, in particular, the potential adverse effects of the medication.

Reference: http://www.neurology.org/content/62/8/1252.full.pdf+html

# 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
- Adequate trial of short-acting opioid analgesics (1-2 weeks) before use of controlled rele
- Not for PRN 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

#### 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.

### **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.

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below:

http://www.nccn.org/professionals/physician\_gls/f\_guidelines.asp

### Oxycodone ER (OxyContin)

Top of Page

#### **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 opiod, 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,
  - d. Paralytic ileus
  - e. Head injury
  - f. Hypotension
  - g. Sleep deprivation.

Top of Page

#### Indications (FDA approved)

- Moderate pain
- Severe pain

#### Non-FDA approved

- Arthralgia
- Bone pain
- Dental pain
- Diabetic neuropathy

- Headache
- Migraine
- Myalgia
- Neuropathic pain
- Postherpetic neuralgia