

PA and Step Therapy Criteria

Amylase/Lipase/Protease (such as CREON) -- FOR INFORMATION ONLY

Indications (FDA approved)

Exocrine pancreatic insufficiency due to:

- o cystic fibrosis,
- o chronic pancreatitis
- o postpancreatectomy,
- o ductile obstruction due to cancer
- o pancreatic insufficiency
- o or other such conditions

Indications, other (Non-FDA approved) – NOT PA approvable

- Pancreatic cancer
- Post-gastrointestinal bypass surgery

Strength

- Based on Lipase units

Products Available for PA 2/15/2011

Recommended --

- Amylase/Lipase/Protease 4,200un to 24,000un
- Pancrelipase (delayed release) 5,000un
- Pan-2400 (OTC) 9,816un

More costly and not recommended unless higher doses required – brand and multisource brand --

- o Pancreaze (delayed release) 4,200un; 10,500un; 16,800un; 21,000un
- o Zenpep (delayed release) 5,000un; 10,000un; 15,000; 20,000un
- o CREON (delayed release) 6,000un; 12,000un; 24,000un

Recommended dosing (stepwise dosing):

- Start: 500 lipase **units/kg** PO w/ meals/snacks, --
Titrates to desired effect;
- Max: 2500 lipase units/kg/meal;
10,000 lipase **units/kg/day**;
4000 lipase **units/g fat** ingested/day;
- Alternate dosing: 500-4000 lipase **units/g fat** ingested/day PO div w/ meals/snacks;
- Information: snack dose usually half of meal dose;

Recommended dosing instructions

Patients should be advised to:

- Take with meals or snacks
- Take with sufficient liquid
- Not to cut, crush or chew
- Swallow immediately
- Caps can be sprinkled on pH 4 or less soft food

Bioequivalency Issue

- Products are not bioequivalent. (See Recommended products above)
- Variability may exist from batch to batch of the same product.
- Delayed Release products are required to contain 90% to 165% of labeled Lipase activity.

Side Effects

- Constipation

- Nausea
- Abdominal cramping
- Diarrhea
- Allergic reactions (from beef, pork, pineapple, and/or papaya)
- Decreased absorption of iron salts
- Folic acid deficiency
- Hyperuricosuria with high doses
- Hyperuricemia with high doses

WARNINGS, PRECAUTIONS, and CONTRAINDICATIONS -- check that drug is not contraindicated due to these warr

- **Fibrosing Colonopathy:**
 - Fibrosing colonopathy has been reported following treatment with different pancreatic enzyme products, usually over a prolonged period of time and most commonly reported in pediatric patients with cystic
 - Patients with fibrosing colonopathy should be closely monitored because some patients may be at risk of progressing to stricture formation.
 - It is generally recommended, unless clinically indicated, that enzyme doses should be less than 2,500 lipase units/kg of body weight per meal (or less than 10,000 lipase units/kg of body weight per day) or less than 4,000 lipase units/g fat ingested per day.
 - Doses greater than 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day) should be used with caution and only if they are documented to be effective by 3-day fecal fat measures that indicate a significantly improved coefficient of fat absorption.
 - Patients receiving higher doses than 6,000 lipase units/kg of body weight per meal should be examined and the dosage either immediately decreased or titrated downward to a lower range.
- **Potential for Irritation to Oral Mucosa:**
 - Care should be taken to ensure that no drug is retained in the mouth.
 - Drug should not be crushed or chewed or mixed in foods having a pH greater than 4.
 - The soft food mixture should be swallowed immediately and followed with water or juice to ensure
- **Potential for Risk of Hyperuricemia:**
 - Caution should be exercised when prescribing Creon to patients with gout, renal impairment, or hyperuric
 - Porcine-derived pancreatic enzyme products contain purines that may increase blood uric acid levels.
- **Potential Viral Exposure from the Product Source:**
 - Products are sourced from pancreatic tissue from swine used for food consumption.
 - The risk that products will transmit an infectious agent to humans has been reduced by testing for certain viruses during manufacturing and by inactivating certain viruses during manufacturing, there is a theoretical risk for transmission of viral disease, including diseases caused by novel or unidentified viruses.
 - However, no cases of transmission of an infectious illness associated with the use of porcine pancreatic extracts have been reported.
- **Allergic Reactions:**
 - Allergy to proteins of porcine (pig) origin.
 - Some products are made with beef, pineapple, papaya – alert to allergies
 - Rarely, severe allergic reactions including anaphylaxis, asthma, hives, and pruritus
 - The risks and benefits of continued treatment in patients with severe allergy should be taken into consideration with the overall clinical needs of the patient
- **Acute pancreatitis**
- **Chronic pancreatic diseases**

Anemia Agent (Epoetin)

PA Criteria based on CMS National Coverage Decision

- Administration
 1. Initiation Period (first 4 weeks)
 - a. Hb level < 10 g/dL
 - b. EPO 40K units once weekly or 150 units/kg three times weekly covered for up to 4 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,

Regarding the choice of Epoetin alfa or Darbepoetin alfa: Note that the ASH/ASCO 2007 clinical practice 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:
 1. **Statement that the patient was informed of the risk for CHF,MI and death 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 -- MSN is NOT an insurance so inform the patients that they are not covered on any
2. ~~Apply to~~ 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.

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 above):
 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

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 (MSN specific clinical addition) radiation = 8mg daily to TID

Non-FDA Approved indications (Not approvable by MSN)

- 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 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:

goals -- OR

2. Intractable and unrelenting cough daily for > 2 weeks while on ACEI -- OR

has

tried ACEI

- **If patient has CKD, there must be documentation of GFR and stage level of > 2 CKD**
 - 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 -- MSN is NOT an insurance so inform the patients that they are not covered on any
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.

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
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 -- MSN is NOT an insurance so inform the patients that they are not covered on any
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.

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
6. The effectiveness of Clonazepam in long-term use, that is, for more than 9 weeks, has not been systematically studied in controlled clinical trials. The physician who elects to use Clonazepam for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

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

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

OPTIONS FOR ANXIETY PRESCRIBING:

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

EXJADE (Deferasirox)

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

Request:

- Serum iron
- Ferritin
- For dosing:
 - LFTs (Liver function tests)
 - Creatinine/BUN
 - Urine analysis / urine osmolality

Max dose = 40 mg/kg/day

Hydrocodone/APAP (Vicodin, Norco)

PA Criteria -- (please see product formulation recommendations and changes below)

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

Product APAP Formulary Recommendations and Changes 2012-2013

FDA Announcement concerning APAP Jan 13, 2011

The U.S. Food and Drug Administration is asking manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule. [see link below for full statement]

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239894.htm>

- Currently on the formulary are: Hydrocodone with APAP of 300mg;325mg;500mg;600mg;660mg;and 750mg
- Vicodin has 300mg APAP in its various formulations and there is NO CURRENT GENERIC available as of Jan 2
- Norco has equivalent dosages of hydrocodone as Vicodin with 325mg APAP in all its formulations and is currentl
 - Norco currently has a generic equivalent in the marketplace

Mupirocin (Bactroban) 2% Nasal Ointment

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 nares?
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 infection?

Note

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

**Neuropathic Pain (For reference only as all steps are not included in the MSN formulary.)
See separate step therapies for Gabapentin (Neuropathic Pain or Anticonvulsant).**

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 -- MSN is NOT an insurance so inform the patients that they are not covered on any
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**

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%)**

❖ **Step 11 Capsaicin, Clonidine, Dextromethorphan, Mexiletine: Use only if adequate trial of First-Line treatments Steps 1-5 AND Second-Line Steps 6-8 ineffective**

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

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 pain
- Adequate trial of short-acting opioid analgesics (1-2 weeks) before use of controlled release opioid
- 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:

1. Dworkin, Robert et al. "Advances in Neuropathic Pain Neurological Review. Archives of Neurology. Nov. 2003. Vol. 60(11). Pp 1524-1534
2. http://www.guideline.gov/summary/summary.aspx?doc_id=4671
3. Stern, C.S. Gabapentin (Neurontin®) for the Treatment of Neuropathic Pain Syndromes 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.
3. The medication must be included in the chemotherapy drugs based on the National Comprehensive 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.

Category 3: Including the recommendation has engendered a major disagreement among the panel members.

3. Reference: The National Comprehensive Cancer Network (NCCN) guidelines can be found at the url below:
http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

Oxycodone ER (OxyContin)

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
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.

Indications (FDA approved)

- Moderate pain
- Severe pain

Non-FDA approved

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

Oxycodone IR (Immediate Release Tablets) (Oxy IR)

PA Criteria for Immediate Release TABLETS (NMT 60 tablets and NMT 30 day supply)

1. FDA-labeled indication is for chronic pain levels from moderate to severe.
2. Limited use of short-acting opioids only for appropriate control of breakthrough pain.
3. A Schedule II controlled medication, therefore needs prior authorization.
4. Use only for moderate to severe pain.
5. To be used in a stepwise fashion starting with non-opioid analgesic, short-acting opioid, and then extended release opioid. Please follow step therapy out-lined above in the Neuropathic Pain Section.
 - Adequate trial of short-acting opioid analgesics (1-2 weeks) before use of controlled release opioid.
 - Increase dose indicated if pain reduced but no improvement of function.
6. To be used only if adequate trials in First Line Therapy Steps 1-2 are ineffective.
7. Not for use on PRN basis.
8. Not for use in the first 12 to 24 hours of surgery.
9. Not for mild pain.
10. Monitor for side effects closely.
11. Monitor for depression and do NOT use with depression.
12. 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

Indications (FDA approved)

- Moderate pain
- Severe pain

Non-FDA approved

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

References:

1. Dworkin, Robert et al. "Advances in Neuropathic Pain Neurological Review. Archives of Neurology. Nov. 2003. Vol. 60(11). Pp 1524-1534
2. http://www.guideline.gov/summary/summary.aspx?doc_id=4671

Anticonvulsants – Prior Authorization / Step Therapy Criteria

Step Therapy for FDA approved indications sorted by seizure types:

Patients with newly diagnosed epilepsy:

- Step 1 - Valproic acid, divalproex, phenobarbital, phenytoin, or lamotrigine use with an ADEQUATE TRIAL
- Step 2 - Clonazepam and topiramate

Patients with partial/mixed epilepsy:

- Step 1 - Valproic acid, divalproex, lamotrigine, topiramate, carbamazepine, oxcarbazepine, or lamotrigine use with an ADEQUATE TRIAL (defined below)
- Step 2 - Gabapentin, Levetiracetam, Phenytoin, Tiagabine

Patients with refractory partial seizures:

- Clonazepam, Phenobarbital, or Phenytoin use with an ADEQUATE TRIAL (defined below)
- Step 2 - Gabapentin, Levetiracetam, Phenytoin, Tiagabine

Patients with refractory generalized tonic-clonic seizures:

- Step 1 - Carbamazepine, Lamotrigine, Valproic acid, or Topiramate use with an ADEQUATE TRIAL (defined below)
- Step 2 - Levetiracetam and Oxcarbazepine

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>

PA Criteria:

******Note: Patients with no prior history of anticonvulsants must be referred to medical director.**

1. Old AEDs (valproic acid, phenytoin, carbamazepine, etc) should be used prior to consideration of
2. Titrate older AEDs (valproic acid, phenytoin, carbamazepine, etc) to optimal dose, until treatment is resistant with ADEQUATE trials as defined below.
3. Initiate levetiracetam on a low dose and gradually titrate the dose.
4. Reduce dose given to patients with renal impairments.
5. Titration of levetiracetam should be carefully monitored and observed for side effects.
6. Do not use medication if patient is hypersensitive to the drug or its ingredients.
7. For new patients enrolled in the program and currently on levetiracetam treatment, please refer to medical director for prior seizure therapy.

Indications (FDA approved)

- Myoclonic seizures
- Partial-onset seizures
- Primary generalized tonic-clonic seizures

Non-FDA approved

- Bipolar Disorder
- Bipolar disorder-manic or mixed episodes (adults)
- Bipolar disorder-depressive episodes (adults)
- Bipolar disorder-Rapid cycling (adults)
- Tardive-dyskinesia
- Migraine

Oral Administration:

1. Levetiracetam should be taken as directed, do not crush or chew tablet unless directed.
2. Do not use broken tablets that have been broken within several days.
3. Take levetiracetam twice a day and at the same time each day.
4. Do not double dose if a dose is missed.

Recommended Dose Titration:

1. Start with a low dose of 1000 mg a day.
2. If needed, increase the dose by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg.

Discontinuation of Therapy:

1. Do not immediately discontinue levetiracetam abruptly, gradually lower the dose of levetiracetam to reduce the risk of seizures.

Renal patients:

1. Patients with CrCl less than 15 mL/min should have their dose reduced proportionally to the CrCl levels.
2. Patients on hemodialysis, use CrCl levels to estimate the maintenance dose.

WARNINGS, PRECAUTIONS, and CONTRAINDICATIONS -- check that drug is not contraindicated due to these warnings

***** There is a safety monitor program (REMS) associated with the use of levetiracetam.**

1. Patients may experience somnolence, asthenia, dizziness, weakness, and coordination difficulties occurring most frequently in the first 4 weeks of treatment.
2. Patients may experience behavioral change, increase in suicide thoughts, and coordination difficulties.

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.

Gabapentin (Neurontin) - Anticonvulsant (see separate criteria for Neuropathic Pain)

PA Criteria for Seizures

1. Old AEDs (valproic acid, phenytoin, carbamazepine, etc) should be used prior to consideration of
2. Titrate older AEDs (valproic acid, phenytoin, carbamazepine, etc) to optimal dose, until treatment is resistant or ineffective with ADEQUATE trials as defined below.
3. Initiate gabapentin on a low dose and gradually titrate to the optimal dose.

Indications (FDA approved)

- Epilepsy
- Postherpetic neuralgia

Non-FDA approved

- Agitation in dementia
- Alcohol Withdrawal
- Bipolar disorder
- Cocaine withdrawal
- Diabetic neuropathy
- Fibromyalgia
- Headaches
- Hiccups (singultus)
- Hot flashes (cancer related)
- Hot flashes (postmenopausal)
- Hyperhidrosis
- Idiopathic muscle cramps
- Nausea
- Neuralgia/Neuropathy/Chronic Pain
- Prevention of migraine (adult/children/adolescent)
- Prevention of spinal opioid-related pruritus
- Pruritus (brachioradial)
- Pruritus (cholestatic)
- Pruritus (uremic)
- Rectal administration
- Restless legs syndrome
- Tremors in multiple sclerosis

Oral Administration:

1. Gabapentin may be taken orally with or without food.
2. Do not use broken tablets that have been broken within several days.
3. Do not chew or crush tablet, unless directed by healthcare professional.
4. The maximum time between each dose should not be greater than 12 hours.

Recommended Dose Titration:

1. Start with a low dose of 300 mg 3 times a day
2. If needed, increase the dose using 300 or 400 mg capsules or 600 or 800 mg tablets 3 times a day.
3. The maximum recommended dose is 1800 mg daily, divided into 3 doses.

Discontinuation of Therapy:

1. Do not immediately discontinue gabapentin.
2. Gabapentin dose should be reduced, discontinued, or substituted with alternative medicine and should be gradually changed over the period of 1 week (Longer duration may be used at the discretion of the health care

Renal patients:

1. Patients with CrCl less than 15 mL/min should have their dose reduced proportionally to the CrCl level. page 13 of 30

2. Patients on hemodialysis, use the CrCl to estimate the maintenance dose.

WARNINGS, PRECAUTIONS, and CONTRAINDICATIONS -- check that drug is not contraindicated due to these warr

***** There is a safety monitor program (REMS) associated with the use of gabapentin.**

1. Do not use medication if patient is hypersensitive to the drug or its ingredients.
2. Antiepileptic drugs may increase the risk of suicidal thoughts or behavior in patients.
3. Children between 3-12 years is associated with the occurrence of CNS-related adverse reactions, which include emotional lability; hostility; thought disorder; hyperkinesia
4. Do not abruptly stop use of anticonvulsants due to increase risk of seizure frequency.
5. Patient may feel dizzy, somnolence and other symptoms or signs related to CNS depression.
6. Gabapentin is excreted renally by the kidney and may have an increase in toxicity with patients with impaired
7. Gabapentin is secreted in human milk; therefore, it should only be used in nursing women where the benefits outweigh the risks.

Drug Interactions

1. Gabapentin bioavailability is reduced when used with antacids by 20%. Take gabapentin 2 hours following administration of antacid.
2. Cimetidine alters the renal excretion of gabapentin and creatinine.
3. Hydrocodone administered with gabapentin increases the concentration of gabapentin and decreases the hydrocodone concentration and maximum concentration.
4. Coadministration of gabapentin with morphine increases the concentration of gabapentin by 44%.
5. Coadministration of gabapentin with norethindrone resulted in an increase of the maximum concentration of norethindrone by 13%.

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.

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

Migraines

PA criteria and Step Therapy for Migraine:

I. First Line Therapy:

- ❖ **Step 1 Acetaminophen, Aspirin, NSAIDs**
- ❖ **Step 2 NSAIDs/APAP/ASA**

Patient OPTIONS FOR Migraine PRESCRIBING:

1. Apply to PAP program -- MSN is NOT an insurance so inform the patients that they are not covered on any insurance program.
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 1-2 ineffective

- ❖ **Step 3 Triptans (Sumatriptan) oral tablets .**
- ❖ **Step 4 Adjunctive therapy such as caffeine or metoclopramide.**

III. Third-Line therapy: Only if adequate trial of First-Line treatments and Second-Line treatments are ineffective

- ❖ **Step 5 Intravenous (IV) dihydroergotamine (DHE) with metoclopramide for nausea**
- ❖ **Step 6 Chlorpromazine, valproate sodium IV<Magnesium Sulfate IV< or prochlorperazine**
- ❖ **Step 7 Dexamethasone**
- ❖ **Step 8 Intranasal lidocaine**
- ❖ **Step 9 Ketorlac**
- ❖ **Step 10 Lidoderm Patch (Lidocaine 5%)**

- ❖ **Step 11 Opiates: Use only if adequate trial of First-Line Therapy Steps 1-2 AND Second-Line Steps 3-4 AND Third-Line therapy Step 5-10 are ineffective**

NOTES for Migraine guidelines for the use of opioid:

PA Criteria for Opioid Use:

- Schedule 2 controlled drug: requires PA
- Restricted to use only after adequate trial of Step 1-9 OR if diagnosis of moderate-severe pain.
- Adequate trial of short-acting opioid analgesics (1-2 weeks) before use of controlled release opioid
- Do not use as on an as needed base. (No 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:

1. <http://guideline.gov/content.aspx?id=14440&search=migraines+and+headache>

Omeprazole

PA Criteria for Omeprazole Use:

- **OTC Omeprazole for 8 weeks ONLY ... then refer to PAP**
- For Reference Use ONLY -- Prilosec OTC ... However, Omeprazole Generic is available OTC also
- Caution: contraindicated in patients that are hypersensitive to Omeprazole
- PPI Use:
 - Reduction of stomach acid
 - Esophagitis
 - GI bleed prophylaxis

Gabapentin (Neurontin) For Neuropathic Pain (see separate criteria for Anticonvulsant)

PA Criteria

1. Please follow Step Therapy found to the left (starting from Neuropathic Pain 1. First Line Therapy) for Neuropathic Pain Guidelines.
2. Gabapentin should be considered after first line therapy Step 1-5 (to the left) has failed treatment after ADEQUATE trials. Therefore, Gabapentin is used in Step 6.
3. Do not use medication if patient is hypersensitive to the drug or its ingredients.
4. Gabapentin is not FDA approved for neuropathic pain, but may be used if Neuropathic guidelines for step therapy are followed.

Indications

Neuropathic Pain

***Gabapentin is not approved by the FDA for neuropathic pain. Please use Step Therapy guideline for gabapentin use in neuropathic pain.

Non-FDA approved

- Agitation in dementia
- Alcohol Withdrawal
- Bipolar disorder
- Cocaine withdrawal
- Diabetic neuropathy
- Fibromyalgia
- Headaches
- Hiccups (singultus)
- Hot flashes (cancer related)
- Hot flashes (postmenopausal)
- Hyperhidrosis
- Idiopathic muscle cramps
- Nausea
- Neuralgia/Neuropathy/Chronic Pain
- Prevention of migraine (adult/children/adolescent)

- Prevention of spinal opioid-related pruritus

- Pruritus (brachioradial)
- Pruritus (cholestatic)

- Pruritus (uremic)

- Rectal administration
- Restless legs syndrome

- Tremors in multiple sclerosis

Oral Administration:

1. Gabapentin may be taken orally with or without food.
2. Do not use broken tablets that have been broken within several days.
3. The maximum time between the three times daily dose should not be greater than 12 hours.

Recommended Dose Titration:

1. Start with a low dose of 300 mg 3 times a day
2. If needed, increase the dose using 300 or 400 mg capsules or 600 or 800 mg tablets 3 times a day.
3. The maximum recommended adult dose is 1800 mg daily, divided into 3 doses.

Discontinuation of Therapy:

1. Do not immediately discontinue gabapentin.
2. Gabapentin dose should be reduced, discontinued, or substituted with alternative medicine gradually and changed over the period of not less than one week (Longer duration may be used at the discretion of the health care provider).

Renal patients:

1. Patients with CrCl less than 15 mL/min should have their dose reduced proportionally to the CrCl levels.
2. Patients on hemodialysis, use the CrCl to estimate the maintenance dose.

WARNINGS, PRECAUTIONS, and CONTRAINDICATIONS -- check that drug is not contraindicated due to these warnings

***** There is a safety monitor program (REMS) associated with the use of gabapentin.**

1. Do not use medication if patient is hypersensitive to the drug or its ingredients.
2. Antiepileptic drugs may increase the risk of suicidal thoughts or behavior in patients.
3. Children between 3-12 years is associated with the occurrence of CNS-related adverse reactions, which include emotional lability; hostility; thought disorder; hyperkinesia
4. Do not abruptly stop use of anticonvulsants due to increase risk of seizure frequency.
5. Patient may feel dizzy, somnolence and other symptoms or signs related to CNS depression.
6. Gabapentin is excreted renally by the kidney and may have an increase in toxicity with patients with impaired renal function.

7. Gabapentin is secreted in human milk; therefore, it should only be used in nursing women where the benefits outweigh the risks.

Drug Interactions

1. Gabapentin bioavailability is reduced when used with antacids by 20%. Take gabapentin 2 hours following administration of antacid.

2. Cimetidine alters the renal excretion of gabapentin and creatinine.
3. Hydrocodone administered with gabapentin increases the AUC of gabapentin and decreases the hydrocodone AUC value and Cmax.

4. Coadministration of gabapentin with morphine increases the AUC of gabapentin by 44%.
5. Coadministration of gabapentin with norethindrone resulted in an increase of the Cmax of norethindrone by 13%

Sumatriptan (Tablets) (Imitrex)

PA for Sumatriptan Tablets

1. PA for not more than 9 tablets per prescription and not more than 2 refills.
2. Standard directions: 1 tablet at onset of migraine- repeat in 2 hours as needed NMT 200mg/day.
3. Maximum of 8x 25mg, 4x 50mg, and 2x 100mg tablets

Indications (FDA approved)

- Migraines

Non-FDA approved

- Migraines in children/adolescents

Oral Administration:

1. Sumatriptan should be taken orally with or without food.

Recommended Dose:

1. Start with a dose of 25mg, 50 mg, or 100mg.
2. Repeat dose if needed AFTER 2 hours.
3. Do not exceed a total daily dose of 200 mg.
4. NOT approved for use in children according to prescribing information.

Renal Function impairment

1. Administer with caution.

Hepatic Function impairment

1. Contraindicated in severe hepatic impairment.
2. Maximum dose is 50 mg single dose.

Contraindications:

1. Coadministration of MAO-A inhibitors or use within 2 weeks of discontinuation of an MAO-A inhibitor.
2. History, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes, other significant underlying cardiovascular diseases, uncontrolled hypertension, hemiplegic or basilar migraine.
3. Concomitant use of ergotamine-containing or ergot-type medication (eg, dihydroergotamine, methysergide)
4. Concurrent use within 24 hours of another 5-HT₁ agonist
5. Hypersensitivity to sumatriptan or any of its component.

MSN Prior Authorization Criteria Updated

Anemia Agent (Epoetin)

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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

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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 -- MSN is NOT an insurance so inform the patients that they are not covered
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.

MSN Prior Authorization UPDATED

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 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

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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 (MSN specific clinical addition) radiation = 8mg daily to TID

Non-FDA Approved indications (Not approvable by MSN)

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

Antihypertensives: (For reference only.)

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Step Therapy for uncomplicated HTN:

- Step 1 – Thiazide Diuretics

MSN Prior Authorization UPDATED

- 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 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

MSN Prior Authorization UPDATED

OPTIONS FOR BRANDED PRESCRIBING:

1. Apply to PAP program -- MSN is NOT an insurance so inform the patients that they are not covered
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.

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

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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 -- MSN is NOT an insurance so inform the patients that they are not covered
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.

MSN Prior Authorization UPDATED

Clonazepam – Prior Authorization / Step Therapy Criteria

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

EXJADE

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

- Serum iron
- Ferritin

MSN Prior Authorization UPDATED

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

Max dose = 40 mg/kg/day

MSN Prior Authorization UPDATED

Hydrocodone/APAP

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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

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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 infection?

Note

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

MSN Prior Authorization UPDATED

formulary.)

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

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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 -- MSN is NOT an insurance so inform the patients that they are not covered
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.

MSN Prior Authorization UPDATED

➤ 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 release
- 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.

MSN Prior Authorization UPDATED

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)

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

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Indications (FDA approved)

- Moderate pain
- Severe pain

Non-FDA approved

- Arthralgia
- Bone pain
- Dental pain
- Diabetic neuropathy

MSN Prior Authorization UPDATED

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