Drug Coverage Criteria

Prior Authorization Criteria

Unless specifically stated, prior authorization requirements of a class of drugs apply to all NEW drugs added to the class.

Aciphex (Rabeprazole)

See Proton Pump Inhibitors

Allegra (fexofenadine)

See Anti-Histamines

Amphetamines

Indications: treatment of hyperkinesis (Diagnosis Code 314 or 429.82), attention deficit disorders (Diagnosis Code 314) or narcolepsy (Diagnosis Code 347)

Restriction Criteria: The diagnosis must appear on the prescription and the claim.

Anabolic Steroids

Prior authorization requirement: FDA indications.

Androgens

Exclusion: establishment of gender reassignment (transsexual) unless the individual's sex was changed by court order.

Restriction Criteria: A diagnosis is required on all prescriptions and claims for androgens when prescribed for patients under 40 years of age.

Anti-Cancer agents

Medicaid will normally reimburse claims for oral anti-cancer agents except in certain instances for Medicare/Medicaid dual eligible recipients.

1. Cancer. If the patient is dual eligible, Medicare will pay for these oral anti-cancer agents when they are used to treat cancer, and Medicare must be billed first. The diagnosis code range for Cancer is 239.0-239.9. Claims for oral anti-cancer agents for Medicare/Medicaid recipients will be denied without a diagnosis code.

2. Other than cancer. Please provide the diagnosis code: i.e. Arthritis diagnosis code is 716.9. This will prevent unnecessary denials of these claims by Medicaid.

3. Off label uses. Oral chemotherapy (anti-cancer) drugs methotrexate and cyclophosphamide have been identified by HCFA as drugs that may also be used in immunosuppressive therapy for patients who have had organ transplants. If the patient is dual eligible, Medicare will pay for these anti-cancer agents when they are used in immunosuppressive treatment. Medicare must be billed first. Medicaid claims for transplant recipients with a diagnosis code for transplants: V42.0 – V42.9, 996.0-996.52, 996.8 will be denied. If claims are submitted to the Medicaid program without a diagnosis code, they will be rejected to bill Medicare first.

Anti-Epileptics

To avoid any generic substitutions for anti-epileptic indications and to comply with the HCFA regulations, prescribers should note on the prescription if the brand is medically necessary.

Note:
Refer to the Provider Manual, Chapter 8, Billing and Authorization Requirements, Federal Upper Limit (FUL) for general policy.

Anti-Histamines

Single source non-sedating oral drugs:

Allegra (fexofenadine)
Claritin (Loratadine)
Zyrtec (Cetirizine)
Combination products of the above

Indications:

Relief of allergic rhinitis or chronic urticaria.

Note:

1. OTC product(s) listed on the OTC formulary are available without prior authorization for FDA approved indications (Appendix);

2. Generic prescription products are available without prior authorization for FDA approved indications;

Prior Authorization requirement:

For single source prescription oral non-sedating anti-histamines:

1. At least 2 generically available products have shown to be ineffective;

2. Serious side effects have developed or are likely to develop with available generic agents. These side effects are included in the prior authorization form;

3. Diagnosis is allergic rhinitis or chronic urticaria.

4. Patient's age is 6 years or older.

Note: Once a prior authorization has been approved for one of the drugs in this class, another agent may be tried if it was listed on the prior authorization form originally as an alternative.

Anti-Leprotic Medications

Medications, which are prescribed for the treatment of leprosy, are not cover by the Medicaid Program. The Hansen's Disease Program which is part of the Department of Health, provides these medications free-of-charge to recipients. Prescribers should refer their patients to the Hansen's Disease Program for follow-up and medications.

Note: If these medications are being used to treat other conditions, a diagnosis code, other than for Hansen's Disease (030.0-030.3, 030.8-030.9), is required for the claim to be processed. If no diagnosis code is provided, the claim will be rejected.

Appetite Suppressants (Anorexiants)

Prior Authorization Requirements:

1. Patient's height and weight or BMI;

2. Patient's program for weight loss.

3. For additional and/or specific criteria for Meridia and Xenical, look under specific drug name.

Arava (Leflunomide)

Indications:
Active rheumatoid arthritis (Diagnosis Code 714.0)

Restriction Criteria:
Arava is available without prior authorization if prescribed by a rheumatologist for the diagnosis of rheumatoid arthritis (diagnosis code 714.0).

Prior Authorization Requirements:

1. Diagnosis of active rheumatoid arthritis and

2. Treatment with methotrexate and at least one (1) other disease modifying anti-rheumatic drug (DMARD) including antimalarials, gold, D-penicillamine, and azathioprine is not adequate, effective or medically appropriate.

3. Provide the following information on the Request for Medical Authorization (Form 1144):

   A. State treatment with methotrexate has not been adequate or effective or is not medically appropriate. If not medically appropriate, explain.

   B. Provide the name of at least one (1) other DMARD that has not been effective.

Atypical Anti-Psychotics

Drugs: Clozapine (generic Clozaril)
Geodon (Ziprasidone)
Risperdal (Risperidone)
Seroquel (Quetiapine)
Zyprexa (Olanzapine)

Indications:

1. Psychotic disorders: management of severely ill schizophrenic patients who fail to respond adequately to standard anti-psychotic drug treatment.

2. Refractory or non-refractory schizophrenics

Restriction Criteria:

Only providers recognized by Medicaid as psychiatrists may prescribe of Clozapine (generic Clozaril), Risperdal, Zyprexa, Seroquel, and Geodon without a prior authorization. Refer to the provider specialty listing in Appendix 6. All other providers must submit a prior authorization request prior to prescribing this class of medication.

Prior Authorization Criteria:

1. For the initial request of Risperdal, Zyprexa, Seroquel, or Geodon,

   A. A DHS Form 1162 - Use of Clozapine (generic Clozaril), Risperdal, Zyprexa, Seroquel, or Geodon - must be attached to the prior authorization request. Indicate the drug being requested;

   B. A Brief Psychiatric Rating Scale (BPRS) report must be attached to the prior authorization request;

   C. A prior authorization request is submitted prior to prescribing this class of medication.

2. After the initial approval for two (2) months, subsequent requests may be made for six (6) month periods. The submission of BPRS must be submitted with the prior authorization request on each subsequent request. Semi-annual narrative reports are required as well.

3. If there is no improvement after three (3) months of using Risperdal, Zyprexa, Seroquel, or Geodon, or if the patient cannot tolerate at least one of these agents due to severe side effects, Clozapine (generic Clozaril) may be approved. Seek initial request of Clozapine (generic Clozaril) as outlined in above in Prior Authorization Criteria 1. A., 1. B., and 1. C. Indicate Clozapine (generic Clozaril) on DHS form 1162 - Use of Clozapine (generic Clozaril), Risperdal, Zyprexa, Seroquel, or Geodon. Document the lack of improvement, on the specific drug, for the time period of use, and/or the severe side effects experienced on the specific drug.

Clozapine (generic Clozaril)

Indication:
Psychotic disorders: Management of severely ill schizophrenic patients who fail to respond adequately to standard anti-psychotic drug treatment.

Geodon (Ziprasidone)

Indications:
Treatment of schizophrenia.

Risperdal (Risperidone)

Indications:
Psychotic disorder: Management of the manifestations of psychotic disorders.

Seroquel (Quetiapine)

Indications:
Psychotic disorder: Management of the manifestations of psychotic disorders.

Zyprexa (Olanzapine)

Indications:

1. Schizophrenia: Management of the manifestations of psychotic disorders;

2. Bipolar mania: short-term treatment of acute manic episodes associated with Bipolar I disorder.

Avonex (Interferon Beta-1)

Indication:
Relapsing Multiple Sclerosis

Prior Authorization Requirement:
For the above indication only.

Axid (Nizatidine)

See H2-antagonists

Azelex (Azelaic acid)

Indication:
Mild to moderate acne

Prior Authorization Requirement:

1. Diagnosis for mild to moderate acne; and

2. Documentation noting other less costly alternatives have been ineffective or inappropriate and these are included in the prior authorization form.

Betaseron (Interferon Beta)

Indication:
Relapsing, remitting multiple sclerosis for ambulatory patients only.

Prior Authorization Requirement:
Documentation for the above indication only.

Bextra (Valdecoxib)

Indication:

1. Osteoarthritis or degenerative joint diseases (Diagnosis code 715.9);

2. Rheumatoid Arthritis (Diagnosis code 714.0); and

3. Primary Dysmenorrhea

Restriction Criteria: Bextra will be available without prior authorization if the following are appropriate:

1. The recipient is over age 60;

2. With a diagnosis code of osteoarthritis or degenerative joint disease (Diagnosis code 715.90 or rheumatoid arthritis (Diagnosis code 714.0); and

3. The recipient's age and the diagnosis code must be submitted with the claim.

Prior Authorization Requirement:

1. For osteoarthritis or rheumatoid arthritis for recipients 60 years of age and under:

    a) Diagnosis of for osteoarthritis or degenerative joint disease or rheumatoid arthritis or primary dysmenorrhea.

2. At least one of the following documented under "Justification" on the Request for Medical Authorization (Form 1144):

    a) History of gastrointestinal bleed or gastric or duodenal ulcer;
    b) History of symptoms of peptic ulcer disease, gastritis, or gastroesophageal reflux (GERD) while on conventional NSAID(s);

    c) Concurrent use of corticosteroids;

    d) Concurrent use of warfarin or heparin; or

    e) History of platelet dysfunction or coagulopathy.

Camptosar (Trinotecan)

Indications:

1. Treatment of colorectal cancer in patients whose disease has recurred or progressed following 5-FU-based therapy; and

2. First-line therapy in combination with the standard treatment, 5-Fluorouracil and leucovorin (5-FU/LV), for metastatic colorectal cancer.

Prior Authorization Requirement:
Documentation of one of the above indications.

Capaxone (Glatiramer)

Indication:
Relapsing, remitting multiple sclerosis

Prior Authorization Requirement:
Documentation for the above indication only.

Celebrex (Celecoxib)

Indications:

1. Osteoarthritis or degenerative joint disease (Diagnosis Code 715.9)

2. Rheumatoid Arthritis (Diagnosis Code 714.0)

3. Familial Adenomatous Polyposis (Diagnosis Code 211.3)

Restriction Criteria: Celebrex is available without prior authorization if the following are appropriate:

1. The recipient is over age 60; and

2. With a diagnosis of osteoarthritis or degenerative joint disease (Diagnosis Code 715.9) or rheumatoid arthritis (Diagnosis Code 714.0) or Familial Adenomatous Poylposis (Diagnosis Code 211.3).

3. The diagnosis code and the recipient's age must be included on the claim.

Prior Authorization Requirements:

A. For Osteoarthritis or Rheumatoid Arthritis for recipients 60 years of age and under:

   1. Diagnosis of osteoarthritis or degenerative joint disease or rheumatoid arthritis and

   2. At least one of the following documented under "Justification" on the Request for Medical Authorization (Form 1144):

      a) History of gastrointestinal bleed or gastric or duodenal ulcer,

      b) History of symptoms of peptic ulcer disease, gastritis, or gastroesophageal reflux (GERD) while on conventional NSAID(s),

      c) Concurrent use of corticosteroids,

      d) Concurrent use of warfarin or heparin, or

      e) History of platelet dysfunction or coagulopathy.

B. For Familial Adenomatous Polyposis in recipients 60 years of age and under:

1. Diagnosis of familial adenomatous polyposis

2. At least one of the following documented under "Justification" on the Request for Medical Authorization (Form 1144):

   a) History of gastrointestinal bleed or gastric or duodenal ulcer,

   b) History of symptoms of peptic ulcer disease, gastritis, or gastroesophageal reflux (GERD) while on conventional NSAID(s),

   c) Concurrent use of corticosteroids,

   d) Concurrent use of warfarin or heparin, or

   e) History of platelet dysfunction or coagulopathy.

Cholestyramine

See Questran

Clozapine (generic Clozaril)

See Atypical Anti-psychotics

Concerta

Indications: treatment of hyperkinesis (Diagnosis Code 314 or 429.82) attention deficit disorders (Diagnosis Code 314)

Restriction Criteria: The diagnosis must be submitted on the claim. The recipient must be between 6 and 12 years of age.

Cyclophosphamide

See Anti-Cancer and Immunosuppressants

Daunoxone (Daunorubicin liposone)

Indication:
First-line cytotoxic therapy for Advanced HIV-related Kaposi's sarcoma. It is not recommended for any patient with less than an advanced case.

Prior Authorization Requirement:
For the above indication only

Enbrel (Etanercept)

Indication:
Moderate to severe active rheumatoid arthritis (Diagnosis Code 714.0)

Restriction Criteria:
Enbrel is available without prior authorization if prescribed by a rheumatologist for the diagnosis of rheumatoid arthritis (diagnosis code 714.0).

Prior Authorization Requirements:

1. Diagnosis of moderate to severe active rheumatoid arthritis and

2. Treatment with methotrexate and at least one (1) other disease modifying anti-rheumatic drug (DMARD) including antimalarials, gold, D-penicillamine, and azathioprine is not adequate, effective or medically appropriate.

3. Provide the following information on the Request for Medical Authorization (Form 1144):

   A. State treatment with methotrexate has not been adequate or effective or is not medically appropriate. If not medically appropriate, explain.

   B. Provide the name of at least one (1) other DMARD that has not been effective.

Estrogens

Exclusion: for establishment of gender reassignment (transsexual) unless the individual's sex was changed by court order.

Restriction Criteria: A diagnosis is required on all prescriptions and claims for estrogens when prescribed for patients under 40 years of age.

Flolan (Epoprostenol)

Indication:
Long term IV treatment of primary pulmonary hypertension in patients with Congestive Heart Failure (CHF) rated New York Heart Association NYHA) Class III (patient only comfortable at rest) or Class IV (continuous symptoms of CHF)

Prior Authorization Requirements:
Documentation of the above indication

Gemzar (Gemcitabine)

Indication:

First-line treatment for locally advanced (non-resectable Stage II or III) or 2.Metastatic (Stage IV) adenocarcinoma of the pancreas.

Prior Authorization Requirement:
Documentation of one of the above indications. Prior authorization criteria for Gemzar (gemcitabine HCl) have been updated to include approval in combination with cisplatin for Stage IIIA, IIIB, or IV non-small cell lung cancer. Other approved indications include Stage II, III, and IV adenocarcinoma of the pancreas.

Genotropin (Somatropin)

See Growth Hormone

Geodon (Ziprasidone)

See Atypical Anti-psychotics

Gonadotropin-Releasing Hormone Analog

Drugs:
Lupron (Leuprolide Acetate)
Viadur (Leuprolide Acetate)

Indications:

1. Prostate Cancer;

2. Endometriosis;

Note:
Zoladex is available without prior authorization for any of the above indications. Zoladex is also indicated for the diagnosis of advanced breast cancer without prior authorization.

Prior Authorization Requirements:

A. For Lupron approval:

1. Documented failure of Zoladex; OR

2. Documented side effects of significant nature with use of Zoladex; OR

3. Diagnosis of Central precocious puberty (CPP) for children**;** OR

4. Diagnosis of Uterine leiomyomata (fibroids) for women.

B. For Viadur approval:

1. Diagnosis of advanced prostate cancer; and

2. Documented successful trial with Zoladex or Lupron depot.

Growth Hormone

Drugs: Genotropin (Somatropin)
Humatrope (Somatropin)
Norditropin (Somatropin)
Nutropin (Somatropin)
Saizen (Somatropin)
Serostim (Somatropin)

Indication:

Somatropin-deficient adults who meet the following criteria:

1. Biochemical diagnosis of somatropin deficiency by means of a negative response to standard growth hormone stimulation test.

2. This deficiency either alone or with multiple hormone deficiencies as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma.

Pediatric criteria:

1. Diagnosis of neurosecretory growth hormone dysfunction or lack of adequate endogenous growth hormone;

2. Diminished peak serum growth hormone response of less than seven (7) mg/ml to, at least, two (2) provocative stimuli;

3. Growth rate less than 4.5cm per year between ages of 0-12;

4. For ongoing therapy, there must be evidence of growth of 1-2' per year to continue therapy;

5. Chronic renal insufficiency resulting in reduced growth hormone and provocative stimuli is not required for this condition.

Prior Authorization Requirement:
Documentation of all of the above criteria.

Serostim (Somatropin)

Indication:
Treatment of AIDS wasting syndrome and cachexia

Prior Authorization requirements:
Documentation of the above diagnosis.

H2-antagonists

Drug: Axid (Nizatidine)
Pepcid (Famotidine)
Zantac (Raniditine)

Indication:

1. Peptic ulcer disease/ gastritis /duodenitis
   - acute dosage up to 2 months
   - maintenance dosage up to one year

   (See the DUR Board Criteria, Appendix 6)

2. GERD (gastroesophageal reflux disease)
   - acute dosage up to 3 months
   - maintenance dosage may be authorized for up to one year

   (See the DUR Board Criteria, Appendix 6)

3. Hypersecretory States (Zollinger-Ellison Syndrome)

4. Others
   - Depends on the situation, medical necessity must be documented on the prior authorization form.

Restriction Criteria:

1. Over-the -counter products which are listed on the OTC Formulary are available without prior authorization (see Appendix 6);

2. Claims for these products will be reimbursed if the diagnosis is one of the following:

   - Peptic Ulcer Disease ICD-9 Code 536.8;
   - Gastroesophageal Reflux Disease (including erosive esophagitis) ICD-9 Code is 530.11;
   - Hypersecretory States (Zollinger-Ellison Syndrome) ICD-9 Code is 251.5.
   - Note: A diagnosis code for heartburn or acid indigestion will not be accepted.

3. If no diagnosis code is provided, the claim will be rejected.

4. Acute dosing must be for limited periods of time with subsequent reduced maintenance dosing. For example:

   Zantac Acute Therapy Guidelines:
   Peptic ulcer/gastritis/duodenitis- Zantac 300mg x 60 days
   GERD- Zantac 600mg x 90 days

   Zantac Maintenance Therapy Guidelines:
   Peptic ulcer/gastritis/duodenitis- Zantac 150mg x up to 1 year
   GERD- Zantac at less than 600mg/day x up to 1 year

Prior Authorization Requirements:

1. Other Prescription Histamine H2 Antagonists will be considered:

   - If cimetidine has been tried at adequate doses for at least 2 weeks unless serious side effects have developed or have a true potential of developing. On the Prior Authorization form, please specify what the side effects were or are projected to be. If cimetidine was ineffective, please note the dose and the period of time it was used.

   - For those patients who are seriously ill and on medications that have a low therapeutic ratio.

   - Some exceptions may be made for school age children.

2. Liquid Zantac (Ranitidine)

   A. Adult:

      1. Documented gastrostomies;

      2. Documented need for H2 antagonist and unable to take cimetidine because of drug-drug interactions (such as cytochrome P-450 pathway, when adjustment of dosage of anti-convulsant medications is not feasible);

      3. Up to 1 year of prior authorization approval.

   B. Children 21 years of age and Under:

      1. Up to 1 year of prior authorization approval;

      2. For maintenance therapy of documented GERD (Gastroesophageal reflux disease);

3. Prior authorizations are not needed for dosage changes during the approved period.

Note: Cimetidine is not totally contraindicated for patients who are also taking other medications, which are metabolized, via the cytochrome P-450 pathway but dose adjustments of these agents may be necessary.

Note: Once prior authorization has been approved for one of the products in this category, the drug may be changed to another product in this class within the approved time period without a new request. However, the alternative(s) must be listed on the original Prior Authorization form.

Herceptin (Trastuzumb)

Indications:

1. Treatment as a single agent for metastatic breast cancer in patients whose tumors over-express the HER2 protein and who have received one or more chemotherapy regimens for their disease

2. Treatment in combination with paclitaxel for metastatic breast cancer in patients whose tumors over express HER2 and who have not received any chemotherapy for their disease

Prior Authorization Requirements:

1. Significant HER2 protein over-expression must be present. The HER2 overexpression test results must be included on the prior authorization form; and

2. Documentation of one of the above indications.

Humatrope (Somatropin)

See Growth Hormone

Hycamtin (Topotecan)

Indication:
Treatment of metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. This is not first-line therapy.

Prior Authorization Requirement:
For the above indication only

Immunosuppressant Drugs

Drugs: oral cyclophosphamide,
oral methotrexate, and
oral prednisone

Indications:

1. FDA approved indications; and

2. Immunosuppressive therapy for patients who have had organ transplants.

Restriction Criteria for Medicare/Medicaid dual eligible recipients:

1. FDA approved indications other than to prevent transplant rejections:

    - A diagnosis code must be on the claim to prevent unnecessary rejection of Medicaid Fee-for-service claim processing;

    - Two (2) examples are as follow.

        1. Diagnosis code for Arthritis is 716.9;

        2. Diagnosis code for Asthma is 493.9.

    - All strengths of these agents are included (i.e. Prednisone 1mg, 5mg, 10mg, 20mg, etc.)

2. For Medicare-covered organ transplants:

    - Medicare will pay for immunosuppressants (all strengths) if used to prevent transplant rejection and Medicare must be billed first;

    - Medicaid will deny claims for immunosuppressant drugs unless an appropriate rejection from Medicare is attached with the claim;

    - Include on Medicaid claims for transplant recipients the diagnosis code for transplants: V42.0 – V42.9; 996.0-996.52, 996.8

    - If claims are submitted to the Medicaid program without a diagnosis code, they will be rejected to bill Medicare first.

Isoniazid

Indications:
FDA approved indications other than pulmonary tuberculosis

Restriction Criteria:
For chemoprophylasis of tuberculosis for children (Diagnosis Code 795.5)

1. Under 19 years of age; and

2. At least one positive tuberculin skin test; and

3. A negative chest x-ray; and

4. Claims for isoniazid must be for products of manufacturers who participate in the Federal Drug Rebate Program; and

5. The diagnosis code 795.5 (tuberculin skin test converter) must be included on the claim for payment to be considered.

Prior Authorization Requirements:
FDA approved indication other than pulmonary tuberculosis (ICD-9 codes: 10.0, 10.8-10.9, 11.0 -11.2, 11.4,11.8,11.9)

Note:
Recipients who have active tuberculosis must continue to be treated at Lanakila Health Center, Leahi Hospital or Local Health Department Tuberculosis Clinics on the Outer Islands. Follow-up of contacts of tuberculin positive individuals is also considered to be the responsibility of the Department of Health.

Lac-hydrin (Ammonium Lactate)

Indication:
Dermatological conditions other than simple dry skin

Restriction Criteria:
Physicians who are registered with Medicaid with the subspecialty of Dermatology will not need a prior authorization.

Prior Authorization Requirement:
Documentation of the dermatological condition.

Lotrisone Cream (Clotrimazole and Betamethasone)

Indication:
FDA approved indications.

Restriction Criteria:
Physicians who are registered with Medicaid with the subspecialty of Dermatology do not need a prior authorization.

Note:

1. The individual ingredients in this combination will be available for compounding in the generic or OTC forms only without prior authorization.

2. If the pharmacist receives approval from the physician to dispense the two (2) single ingredients instead of the Lotrisone, the two (2) products must be compounded together and billed as a single compounded prescription. The pharmacy must supply the NDC numbers and the quantities used, etc., and may bill Medicaid for one dispensing fee plus one compounding fee of $1.50 for mixing the two (2) agents together.

Prior Authorization Requirement:
Documentation of failure or side effects from the compound of the two (2) single ingredients.

Lupron (Leuprolide Acetate)

See Gonadotropin-Releasing Hormone Analog

Meridia (Sibutramine)

Indications:

1. Weight loss in patients with an initial Body Mass Index (BMI) greater than or equal to 30kg/m^2 **OR** greater than or equal to 27kg/m^2 in the presence of at least one other risk factor such as hypertension, sleep apnea, diabetes, dyslipidemia, coronary heart disease or other artherosclerotic diseases;

2. Maintenance of weight loss

Prior Authorization Requirements:

1. Must be for one of the indications noted above; and

2. Used in conjunction with a reduced calorie diet.

3. Provide the following information on the Request for Medical Authorization (Form 1144):

   A. For initial weight loss, state the recipient's BMI or provide the height and weight. If the BMI is equal to or greater than 27kg/m^2 but less than 30kg/m^2, state at least one risk factor;

   B. For subsequent weight loss or for maintenance of weight loss, provide the initial and current BMI; and

   C. State recipient is on a reduced calorie diet.

Note:
Initial approval will be for a maximum of 3 months. If there is weight loss or the recipient has been able to maintain prior weight loss during this initial period, subsequent prior authorization requests may be approved up to a maximum of 6 months.

Methylphenidates

Indications:
Treatment of hyperkinesis (Diagnosis Code 314 or 429.82) attention deficit disorders (Diagnosis Code 314) or narcolepsy (Diagnosis Code 347)

Restriction Criteria:
The diagnosis must appear on the prescription and the claim.

Neo-Calglucon (Liquid Calcium)

Indication:
Calcium deficiency

Prior Authorization Criteria:

1. Replacement of calcium in documented calcium deficient patients that require tube feedings of calcium, etc.

2. Up to 1 year of prior authorization approval.

Nexium (Esomprazole)

See Proton Pump Inhibitors

Nonsteroidal Anti-Inflammatory Drugs

Indications:
FDA approved indications

Note:

1. Over-the-counter products listed on the OTC Formulary are available without prior authorization for FDA approved indications;

2. Generic products are available without prior authorization for FDA approved indications;

3. Based on diagnosis codes and age, selective COX-2 inhibitors are available without prior authorization.

Prior Authorization Criteria:

1. For single source prescription nonsteroidal anti-inflammatory drugs

   A. At least two (2) generically available products have been given adequate trials and have proven ineffective; and

   B. Documentation of the drug, the dose and the length of time for each generic tried is included on the prior authorization form;

   C. If serious side effects developed or have a real potential of developing, document them on the prior authorization form.

2. For selective COX-2 inhibitors, see

   A. Celebrex (Celecoxic)

   B. Vioxx (Rofecoxib)

Note:
Once Prior Authorization has been approved for a single source product in this class, the drug may be changed to another single source product within the approved time period without a new request. However, the alternative(s) must be listed on the original prior authorization form.

Exception:
Toradol (Ketorolac tromethamine) is **not** included in this category since it is generally used for pain and is only authorized for a 5-day supply.

Examples of oral products that were single source but have generics available today are:

Daypro (Oxaprozin)
EC-Naprosyn (Naproxen delayed release)
Lodine (Etodolac)
Oruvail (Ketoprofen SR)
Voltaren (Diclofenac)

Examples of oral products that are single source prescription nonsteroidal anti-inflammatory agents are:

Mobic (Meloxicam)
Relafen (Nabumetone)

Note: Once prior authorization has been approved for one of the products in this category, the drug may be changed to another product in this class within the approved time period without a new request. However, the alternative(s) must be listed on the original Prior Authorization form

Norvasc (Amlodipine)

Indication:

1. Angina

2. May be considered for Hypertension if Adalat CC or other calcium channel blockers have proven to be ineffective after at least a 2-week trial.

3. If Adalat or other calcium channel blocker was discontinued due to significant side effects, note these on the 1144 form. If these were ineffective, please note the dose and the length of time used.

Norditropin (Somatropin)

See Growth Hormone

Nutropin (Somatropin)

See Growth Hormone

Ontak (Denileukin diftitox)

Indications:
Persistent or recurrent cutaneous T-cell lymphoma (CTCL) that's malignant cells expresses the CD25 component of the IL-2 receptor.

Prior Authorization Requirements:

1. Documentation of malignant cells testing positive for CD25 expression;

2. Significant reduction in tumor size should be seen prior to the fourth (4^{th}) course of treatment. Three (3) treatment cycles (of 5 days each) will be approved initially.

Over the counter (OTC) products

See OTC Formulary, Appendix 6.

Pancretin (Alitretinoin)

Indication:
Topical treatment of cutaneous lesions due to AIDS-related Kaposi's Sarcoma (KS)

Prior Authorization Requirement:

1. Systemic anti-KS treatment is not needed. Note on the prior authorization form that no systemic KS treatment is indicated.

2. Systemic treatment would be indicated in such instances of more than ten (10) new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS or symptomatic visceral involvement.

Note: Approval period = 14 weeks. Maximum quantity for the approval period = 3 tubes. Submit another Prior Authorization 1144 form with justification if therapy is needed for longer.

Pepcid (Famotidine)

See H2-antagonists

PHOTOFRIN (Porfimer Sodium)

Indications:

1. Palliation of patients with partially or completely obstructing esophageal cancer who cannot be satisfactorily treated with Nd:YAG laser therapy; and

2. Treatment of microinvasive endobronchial non-small cell lung cancer in patients for whom surgery and radiotherapy are not indicated

Prior Authorization Requirements:
Documentation of one of the above indications

Prevacid (Lansoprazole)

See Proton Pump Inhibitors

Prilosec (Omeprazole)

See Proton Pump Inhibitors

Procardia XL (Nifedipine XL)

Indications:

1. Angina

2. Hypertension if Adalat CC is not effective or was discontinued due to side effects.

Prior authorization requirements:

1. Diagnosis of angina

2. Considered for hypertension if Adalat CC has proven to be ineffective after a trial of at least 2 weeks.

3. If Adalat CC was discontinued due to side effects, note these on the 1144 form. If Adalat CC was ineffective, please note the dose and the length of time used.

Protonix (Pantoprazole)

See Proton Pump Inhibitors

Proton Pump Inhibitors

Drugs: Aciphex
Nexium
Prevacid
Prilosec
Protonix

Restriction Criteria:

1. A 14-day supply of PPIs may be provided without a prior authorization if a diagnosis of H.Pylori is noted on the prescription and claim. ICD-9 codes 008.43 or 041.86 are acceptable diagnosis codes. Any other diagnosis or for a greater length of therapy, prior authorization approval is required.

2. Internists or pediatricians with a subspecialty of Gastroenterology may prescribe PPIs without prior authorization if a diagnosis of gastroesophageal reflux disease (GERD) ICD-9 code = 530.81 is noted on the prescription and the claim. The prescriber's specialty must be registered with the Medicaid program. PPIs prescribed for any other diagnosis regardless of prescriber specialty requires prior authorization approval.

Note:

1. H2 blockers do not have to be tried first for prior authorization of PPIs to be approved for Gastroesophageal Reflux Disease (GERD).

2. If a PPI is prescribed concurrently with a histamine H2-receptor antagonist (Zantac, Pepcid, Axid or Tagamet) or sucralfate (Carafate), it will be considered duplicative therapy and will not be reimbursed if both medications are dispensed by the same provider.

Indications:

1. Duodenal ulcer

2. Erosive or ulcerative GERD

3. Hypersecretory condition

4. Others – depends on the situation; medically necessity must be documented

Prior authorization requirements:

- Duodenal ulcers – 20mg daily for 4 to 8 weeks
- Erosive or ulcerative GERD – 20mg daily for 4 to 8 weeks (an additional 8 weeks may be considered); maintenance 20mg daily
- Hypersecretory conditions
- Other – depends on medical necessity

Note:

❖ If additional lengths of therapy are needed, please justify and provide the long term treatment plan.

❖ If prescribed concurrently with a histamine H2-receptor antagonist (Zantac, Pepcid or Axid) or sucralfate (Carafate), this will be considered duplicative therapy and will not be reimbursable.

NEXIUM (Esomeprazole)

Indications: 1. GERD
2. Erosive esophagitis
3. H. Pylori
4. Others – depends on the situation; medically necessity must be documented

Prior authorization requirements:

- GERD – 20mg daily for 4 to 8 weeks
- Erosive Esophagitis – up to 40mg daily for 4 to 8 weeks; maintenance 20mg daily
- H. Pylori – greater than 14 days supply
- Other – depends on medical necessity

Note:

- ❖ If additional lengths of therapy are needed, please justify and provide the long term treatment plan.

- ❖ If prescribed concurrently with a histamine H2-receptor antagonist (Zantac, Pepcid or Axid) or sucralfate (Carafate), this will be considered duplicative therapy and will not be reimbursable.

PREVACID (Lansoprazole)

Indications:

1. GERD

2. Duodenal Ulcer 3. H. Pylori

3. Gastric Ulcer

4. Erosive esophagitis

5. Hypersecretory Conditions

6. Others - depends on the situation and medical necessity must be documented.

Prior authorization requirements:

- GERD - 30mg daily for up to 8 weeks (an additional 8 weeks if needed) for treatment and 15 mg daily for maintenance.

- Duodenal Ulcer - 15mg daily for 30 days

- H. Pylori – if greater than 14 days of therapy

- Gastric Ulcer – 30mg daily for up to 8 weeks

- Erosive esophagitis – 30mg daily for 8 weeks (an additional 8 weeks if needed) for treatment and 15mg daily for maintenance

- Hypersecretory conditions

- Other conditions – depends on medical necessity

Note:

- ❖ If additional lengths of therapy are needed, please justify and provide the long term treatment plan.

- ❖ If prescribed concurrently with a histamine H2-receptor antagonist (Zantac, Pepcid or Axid) or sucralfate (Carafate), this will be considered duplicative therapy and will not be reimbursable.

PRILOSEC (Omeprazole)

Indications:

1. GERD
2. Duodenal ulcer
3. H. Pylori
4. Gastric ulcer
5. Severe erosive esophagitis
6. Hypersecretory conditions
7. Others – depends on medical necessity

Prior authorization requirements:

- GERD without esophageal lesions – 20mg daily for up to 4 weeks
- GERD with erosive esophagitis -20mg daily for 4 to 8 weeks
- Duodenal Ulcer- 20mg daily for month of therapy (an additional 4 weeks may be considered)
- H. Pylori – longer than 14 days of treatment
- Gastric Ulcer – 40mg daily for 4 to 8 weeks

- Severe erosive esophagitis – 20mg daily 4 to 8 weeks for treatment; 20mg daily for maintenance

- Hypersecretory conditions

- Others – depends on medical necessary

Note:

❖ If additional lengths of therapy are needed, please justify and provide the long term treatment plan.

❖ If prescribed concurrently with a histamine H2-receptor antagonist (Zantac, Pepcid or Axid) or sucralfate (Carafate), this will be considered duplicative therapy and will not be reimbursable.

Protonix (Pantoprazole)

Indications:
Short-term treatment (up to 8 weeks) in the healing and symptomatic relief of erosive esophagitis associated with GERD. For those patients who have not healed, and additional 8 weeks of treatment may be considered

Prior authorization requirements:
Documentation of the above diagnosis

Provide the following information on the Request for Medical Authorization (Form 1144):

1. Diagnosis of erosive esophagitis

2. Initial therapy or second course

The approval will be for a maximum of 40mg daily for 8 weeks per treatment and the number of treatments limited to two per episode.

Note:

- If additional lengths of therapy are needed, please justify and provide the long term treatment plan.

  If prescribed concurrently with a histamine H2-receptor antagonist (Zantac, Pepcid or Axid) or sucralfate (Carafate), this will be considered duplicative therapy and will not be reimbursable.

Protopin (Somatrem)

See Growth Hormone

Provigil

Indications:
Treatment of narcolepsy (Diagnosis Code 347)

Restriction Criteria:
The diagnosis must appear on the prescription and the claim.

Questran (Cholestyramine)

All forms except bulk powder or granular dosage forms were removed from the Formulary. Bars, chewable forms or pre-measured packets were excluded based on the comparable high cost per dose.

Ranitidine

See H2 antagonists

Rebetron (Rebetol [Ribavirin] with Intron A)

Indication:
Treatment of chronic hepatitis C in-patients with compensated liver disease previously untreated with alfa interferon or who have relapsed following alpha interferon therapy

Prior authorization requirements:
All of the following must be present:

1. Compensated Chronic Hepatitis C; and

2. HCV Antibody Positive; and

3. Elevated ALT level

Regranex (Becaplerium)

Indication:
Lower extremity diabetic neuropathic ulcers

Prior authorization requirements:
Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue and beyond and have an adequate blood supply.

Relenza (Zanamivir)

Restriction Criteria:
Five (5) day maximum supply

REMICADE (Infliximab):

Indications:

1. Moderate to severe and fistulating Crohn's Disease

2. Rheumatoid Arthritis (Diagnosis Code 714.0)

Restriction Criteria:
Remicade is available without prior authorization if prescribed by a rheumatologist for the diagnosis of rheumatoid arthritis (diagnosis code 714.0).

Prior Authorization Requirements:

1. For Crohn's Disease

   A. Diagnosis of moderate to severe or fistulating Crohn's Disease

   B. Other conventional agents such as sulfasalazine, mesalamine derivatives, steroids, azathioprine, 6-mercaptopure, or metronidazole are ineffective or are not medically appropriate.

   C. Limits for treatment:

      1) For moderate to severe: maximum one (1) dose only

      2) For fistulating: Maximum three (3) doses

2. For Rheumatoid Arthritis

   A. Diagnosis of rheumatoid arthritis and

   B. Treatment with methotrexate and at least one (1) other disease modifying anti-rheumatic drug (DMARD) including antimalarials, gold, D-penicillamine, and azathioprine is not adequate, effective or medically appropriate.

   C. Provide the following information on the Request for Medical Authorization (Form 1144):

      1) State treatment with methotrexate has not been adequate or effective or is not medically appropriate. If not medically appropriate, explain.

      2) Provide the name of at least one (1) other DMARD that has not been effective.

Note: If the infusion is to be done in the home setting, home pharmacy services and supplies related to the infusion of Remicade must be prior authorized.

RespiGam (Human respiratory syncitial virus [RSV] immune globulin)

Indication:
Prevention of Serious Lower Respiratory Tract Infections caused by Respiratory Syncytial Virus (RSV)

The following guidelines for the prevention of RSV and coverage of this agent by Hawaii QUEST medical plans and the fee-for-service Medicaid Program have been developed by the medical directors in consultation with the University of Hawaii School of Medicine's Pediatric Infectious Disease Group.

Recommended Guidelines

Patients who should be considered for RSV prophylaxis should be in one or more of the following groups:

- Premature infants with BPD and who are on supplemental oxygen and less than eight (8) months chronological age [corrected age of less than six (6) months] as of December of the year of their birth.

- Infants born at less than 32 weeks gestation with a history of one or more respiratory tract infections which required hospitalization who are under eight (8) months age [corrected age of less than six (6) months] as of December of the year of their birth.

- Infants 28 weeks gestation or less and who are less than twelve (12) months of age at the start of the RSV season.

- Infants and children less than two (2) years of age at the start of the RSV season with chronic lung disease (CLD) who were receiving long term medical therapy for treatment of their CLD within six (6) months before the anticipated RSV season.

Recommended Treatment

- Maximum of four (4) monthly doses to start as early as late October and to end no later than March.

- RespiGam is indicated for the PREVENTION of RSV and should NOT be used in-patients who have RSV infections.

Additional Considerations

- The physician must weigh the side effects of this agent against the benefit gained from preventing RSV infections.

- RespiGam should not be administered at the same time as routine childhood immunizations and may interfere with response to immunizations.

- RespiGam is not approved by the Food and Drug Administration (FDA) for use in-patients with congenital heart disease (CHD). RespiGam is contraindicated in cyanotic CHD.

Retin A (Tretinoin)

Indication:
Medically indicated skin conditions including acne and other dermatoses. Retin A is not reimbursable for wrinkles.

Restriction criteria:
Must be for a medically indicated skin condition or dermatoses. Wrinkles are not included.

Risperdal (Risperidone)

See Atypical Anti-psychotics

Rituxan (Rituximab)

Indication:
Relapsed of refractory low-grade or follicular, CD20+, B-cell Non Hodgkin's Lymphoma

Prior authorization requirements:
Documentation of the above diagnosis

Saizen (Somatropin)

See Growth Hormone

Seroquel (Quetiapine)

See Atypical Anti-psychotics

Serostim (Somatropin)

Indication:
Treatment of AIDS wasting syndrome and cachexia (Also see Growth Hormone)

Prior Authorization requirements:
Documentation of the above diagnosis.

Synagis (Palvizumab)

Indication:
Prevention of serious lower respiratory tract infections caused by Respiratory Syncytial Virus (RSV)

The following guidelines for the coverage of this agent by the fee-for-service Medicaid Program have been developed by the medical directors in consultation with the University of Hawaii School of Medicine's Pediatric Infectious Disease Group.

Recommended Guidelines
Patients who should be considered for RSV prophylaxis should be in one or more of the following groups:

- Premature infants with BPD and who are on supplemental oxygen and less than eight (8) months chronological age [corrected age of less than six (6) months] as of December of the year of their birth.

- Infants born at less than 32 weeks gestation with a history of one or more respiratory tract infections which required hospitalization who are under eight (8) months age [corrected age of less than six (6) months] as of December of the year of their birth.

- Infants 28 weeks gestation or less and who are less than twelve (12) months of age at the start of the RSV season.

- Infants and children less than two (2) years of age at the start of the RSV season with chronic lung disease (CLD) who were receiving long term medical therapy for treatment of their CLD within six (6) months before the anticipated RSV season.

Recommended Treatment
- Maximum of four (4) monthly doses to start as early as late October and to end no later than March.

- Synagis is indicated for the PREVENTION of RSV and should NOT be used in patients who have RSV infections.

Additional Considerations
- The physician must weigh the side effects of this agent against the benefit gained from preventing RSV infections.

- Synagis is not approved by the Food and Drug Administration (FDA) for use in-patients with congenital heart disease (CHD).

- As Synagis is given intramuscularly, it must be used with caution in-patients with thrombocytopenia and coagulation disorders.

- A second (2^{nd}) course of Synagis therapy in the following season is rarely indicated.

Tamiflu (Oseltamivir phosphate)

Restriction Criteria:
Authorized for a 5-day supply.

Taxotere (Docetaxel)

Indications:

1. Anthracycline resistant breast cancer

2. Treatment of locally advanced ore metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy

Prior Authorization Requirements:
Documentation of one of the above indications

Toradol (Ketorolac tromethamine)

Indications:
Treatment of acute pain

Restriction Criteria:
Authorized for a 5-day supply per thirty days.

Tritec (ranitidine bismuth citrate)

Indications:
Treatment of active duodenal ulcer associated with H. Pylori infection and used in conjunction with an antibiotic (like Biaxin or other antibiotic) deemed necessary by the prescriber. This is not intended to be prescribed alone.

Restriction criteria:

Tritec is available without prior authorization if the following are appropriate:

1. Diagnosis for H.Pylori (041.86 or 008.43) and

2. Days supply does not exceed 28 days

This information must be included on the claim.

Prior authorization requirements:

- Any diagnosis other than H.Pylori

- If treatment for H.Pylori will last longer than 28 days, justification for the extended therapy must be documented.

Note: In cases of multiple treatments, pharmacists are encouraged to use appropriate drug utilization review considerations.

Valstar (Valrubicin)

Indication:
Bladder Cancer – for intravesical therapy of BCG-refractory carcinoma in situ (CIS) of the urinary bladder in-patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

Prior authorization requirements:
Documentation of the above diagnosis.

Vesanoid (Tretinoin)

Indication:
Acute Promyeloytic Leukemia (APL) for a maximum of 90 days

Prior Authorization requirements:
Documentation for the above diagnosis and period of time

Viadur (Leuprolide Acetate)

See Gonadotropin-Releasing Hormone Analog

Vicoprofen (Hydrocodone w/ibuprofen)

Indications:
Analgesia, acute or chronic

Prior authorization requirements:

1. Documentation of trial and failure on other similar combination products which are much less expensive; and

2. Documentation of acute or chronic pain.

Vioxx (Rofecoxib)

Indications:
1. Osteoarthritis or degenerative joint disease

2. Primary dysmenorrhea

3. Acute pain

Restriction Criteria:

Vioxx is available without prior authorization if the following are appropriate:

1. The recipient is over age 60; and

2. Has a diagnosis of osteoarthritis or degenerative joint disease (Diagnosis Code 715.9). The diagnosis code and the recipient's age must be included on the claim.

Prior authorization requirements for recipients 60 years of age and under:

1. Diagnosis of osteoarthritis or degenerative joint disease, primary dysmenorrhea or acute pain and

2. At least **one** of the following documented under "justification" on the Request for Medical Authorization (Form 1144):

   a.) History of gastrointestinal bleed or gastric or duodenal ulcer,

   b) History of symptoms of peptic ulcer disease, gastritis, or gastroesophageal reflux disease while on conventional NSAID(s),

   c) Concurrent use of corticosteroids,

   d) Concurrent use of warfarin or heparin, or

   e) History of platelet dysfunction or coagulopathy.

Note: For recipients with a diagnosis of acute pain, Vioxx will only be prior authorized for a MAXIMUM of three (3) months. After this time period, the pain will be considered chronic and other management strategies should be considered.

Vitamin B12

Indications:
Vitamin B_{12} Deficiencies

Restriction criteria:
No prior authorization is required if one of the following diagnoses is appropriate:

Malabsorption syndrome of Vitamin B_{12} due to gastrectomy	579.3
Pernicious anemia	281.0
Other Vitamin B_{12} anemias	281.1
Vitamin B_{12} and Folate anemia	281.3
Vitamin B_{12} deficiency	266.2

The diagnosis code must be included on the claim.

Prior authorization requirements:
Document the diagnosis of vitamin deficiency and medical necessity.

Vitamin C

Indications:

1. Scurvy – treatment

2. Acidify the urine for urinary tract infection

Restriction criteria:
No prior authorization is required if the appropriate diagnosis is Urinary Tract Infection. Use one of the following ICD-9 codes: 582.0-582.9; 590.0-590.01; 590.9; 595.1; 595.2.

The diagnosis code must be included on the claim.

Prior authorization requirements:
Document the diagnosis and medical necessity.

VITAMINS, MULTIPLE

Indications:

Restriction criteria:
No prior authorization is required if:

a. The appropriate diagnosis (with ICD-9 code)is:

- Pregnancy or lactation (V22.0-V22.2, V23, 611.6, 675.2, 676.4-676.6, 676.8, or 676.9);or

- End stage renal disease (ESRD) (585)

The diagnosis code must be included on the claim

b. The recipient is residing in a LTC facility;

c. Children under 12 years of age for pediatric multivitamins including those with fluoride

Prior authorization criteria:

Document the diagnosis of a vitamin deficiency and medical necessity with one of the following diagnoses/conditions (with ICD-9 code):

Mental retardation;
Spastic quadriplegia with GI problems;
Tube fed;
Low body weight;
Osteoporosis;
Child under the age of 12 years;
Compromised physical condition such as an elderly patient with poor nutrition, alcoholism with cirrhosis, or an electrolyte imbalance; or
in a SNF on a long-term basis.

XENICAL (Orlistat)

Indications:

1. For patients with an initial Body Mass Index (BMI) greater than or equal to 30kg/m^2 **OR** greater than or equal to 27kg/m^2 in the presence of at least one other risk factor such as hypertension, sleep apnea, diabetes, dyslipidemia, coronary heart disease or other artherosclerotic diseases; and

2. Maintenance of weight loss

Prior Authorization Requirements:

1. Must be for one of the indications noted above; and

2. Used in conjunction with a reduced calorie diet

Provide the following information on the Request for Medical Authorization (Form 1144):

1. For initial weight loss, state the recipient's BMI or provide the height and weight. If the BMI is equal to or greater than 27kg/m^2 but less than 30kg/m^2, state at least one risk factor ;

2. For subsequent weight loss or for maintenance of weight loss, provide the initial and current BMI; and

3. State recipient is on a reduced calorie diet

Note: Initial approval will be for a maximum of 3 months. If there is weight loss or the recipient has been able to maintain prior weight loss during this initial period, subsequent prior authorization requests may be approved up to a maximum of 6 months**.** A daily

multivitamin is recommended while taking Xenical but is not a requirement for prior authorization. A multivitamin will be approved if used in conjunction with Xenical. If a multivitamin is not included on the prior authorization with Xenical and a separate request is submitted, please state it is being used in conjunction with Xenical to expedite approval.

ZANTAC (Ranitidine)

See H2 Antagonists

Zyprexa (Olanzapine)

See Atypical Anti-psychotics

Zyrtec (Cetirizine)

See Antihistamines, non-sedating