Alabama Medicaid
Preferred Drug and Prior Authorization Program

Effective October 1, 2003, as a result of legislation passed in June 2003, the Alabama Medicaid Agency implemented a mandatory Preferred Drug List (PDL). Brand preferred drugs, generics and over-the-counter drugs for classes reviewed covered by Medicaid are available without prior approval. If, however, a non-preferred drug is ordered the practitioner will need to get prior authorization. If approval is given to dispense the non-preferred drug, an authorization number will be given. Antipsychotic and HIV/AIDS drugs are exempted from the PDL.

The following entries contain detailed instructions on completing the Medicaid Prior Authorization Form, as well as answers to frequently asked questions about the Medicaid Pharmacy Program.

Section One: General Information

- **Preferred Drugs**

The following classes of drugs are on the mandatory preferred drug list:

- **ADD/ADHD Agents**
- **Alzheimer Agents**
- **Anxiolytic, Sedative, Hypnotic Agents**
- **Antidepressant Agents**
- **Antidiabetic Agents**
- **Antihyperlipidemic Agents**
- **Antihypertensive Agents**
- **Anti-infective Agents**
- **Cardiac Agents**
- **EENT Antiallergic Agents**
- **EENT Vasoconstrictor Agents**
- **Estrogen Agents**
- **Intranasal Corticosteroid Agents**
- **Narcotic Analgesic Agents**
- **Platelet Aggregation Inhibitor Agents**
- **Respiratory Agents**
- **Skeletal Muscle Relaxant Agents**
- **Skin and Mucous Membrane Agents**
- **Triptan Agents**

Other drug classes will be added as they are reviewed and approved.

- **Stable Therapy**

  Stable therapy applies for all classes listed below for children 18 years old and under. The application for adults is limited to specific classes listed below as stable therapy for all ages. The applicable timeframes can be found below.

  Stable therapy for all ages:

  - **ADD/ADHD Agents-** Approval may be given with consecutive 60 day treatment.
  - **Alzheimer Agents-** Approval may be given with consecutive 90 day treatment.
  - **Antidepressant Agents-** Approval may be given with consecutive 60 day treatment.
  - **Antidiabetic Agents-** Approval may be given with consecutive 60 day treatment.
  - **Antihypertensive Agents-** Approval may be given with consecutive 60 day treatment.
  - **Anti-infective Agents-** Approval may be given with following institutionalization or consecutive 60 day treatment.
  - **Cardiac Agents-** Approval may be given with consecutive 60 day treatment.
  - **Skeletal Muscle Relaxant Agents-** Approval may be given with consecutive 60 day treatment.

  Stable therapy for children 18 years old and under:

  - **2nd Generation Antihistamine Agents-** Approval may be given with consecutive 60 day treatment.
  - **Antihyperlipidemic Agents-** Approval may be given with consecutive 60 day treatment.
  - **Anxiolytic, Sedative, and Hypnotic Agents-** Approval may be given with consecutive 60 day treatment.
  - **EENT Antiallergic Agents-**Approval may be given with consecutive 60 day treatment.
  - **EENT Vasoconstrictor Agents-**Approval may be given with consecutive 60 day treatment.
  - **Estrogen Agents-** Approval may be given with consecutive 60 day treatment.
  - **Intranasal Corticosteroid Agents-** Approval may be given with consecutive 60 day treatment.
  - **Narcotic Analgesic Agents-** Approval may be given with consecutive 60 day treatment.
  - **NSAID Agents-** Approval may be given with consecutive 60 day treatment.
  - **Platelet Aggregation Inhibitors-** Approval may be given with consecutive 60 day treatment.
  - **Proton Pump Inhibitor Agents-** Approval may be given with consecutive 60 day treatment.
  - **Respiratory Agents-** Approval may be given with consecutive 60 day treatment.
  - **SROA Agents-** Approval may be given with consecutive 60 day treatment.

- **Skin and Mucous Membrane Agents-** Approval may be given with consecutive 60 day treatment.
- **Triptan Agents-** Approval may be given with consecutive 60 day treatment.

- **Verbal Requests**

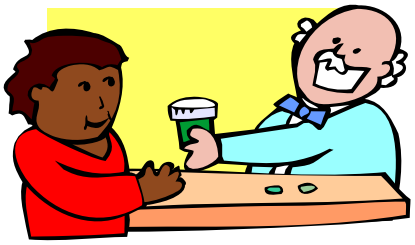
PA requests for the drugs that meet the previous drug usage requirements for approval will be accepted verbally. Verbal PA requests may be initiated by Pharmacists, Physicians or their authorized representative. Any drug requiring additional information or medical justification must be submitted on the required PA form. Drugs that may be requested verbally are listed below:

- **ADD/ADHD Agents**
- **Alzheimer Agents**
- **Anxiolytic, Sedative, Hypnotic Agents**
- **Antidepressant Agents**
- **Antidiabetic Agents**
- **Antihistamine Agents**
- **Antihyperlipidemic Agents**
- **Anti-infective Agents**
- **Cardiac Agents**
- **EENT Antiallergic Agents**
- **EENT Vasoconstrictor Agents**
- **Estrogen Agents**
- **H2 Antagonist Agents**
- **Intranasal Corticosteroid Agents**
- **Narcotic Analgesic Agents**
- **NSAID Agents**
- **Platelet Aggregation Inhibitor Agents**
- **PPI Agents**
- **Respiratory Agents**
- **Skeletal Muscle Relaxant Agents**
- **Skin and Mucous Membrane Agents**
- **Triptan Agents**

- **Paper Requests**

Page one of the Prior Authorization Request form may be submitted alone unless the medication requested is listed on page two. Check the appropriate box at the top of the form to indicate whether one or both pages are being submitted. Acknowledgement of transmission of the second page will assure that the reviewer has all completed material needed to review the request. **A separate form will need to be completed for each drug/nutritional requested.**

- **PA Approval Timeframes**



NSAID - Approval may be given for up to 12 months.
Antihistamine - Approval may be given for up to 12 months.
H2 Antagonist - Approval may be given for up to 12 months for maintenance.
PPI - Approval may be given for up to 12 months for maintenance.
Prevpac® - Approval authorizes a 14 day course of therapy.

Prevacid NapraPac™ - Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

Sustained Release Oral Opioid Agonist - Approval may be given for up to 12 months.

Biological Injectables - Approval may be given for up to 12 months.

Xenical® - Approval may be given for up to 3 months with initial request, and up to 6 months for each subsequent request to a total approval period not to exceed 2 years for the recipient.

Erectile Dysfunction Drugs - Approval may be given for up to 30 days for initial request, with up to 3 months allowed for renewal requests.

Synagis®- Approval may be given for up to 5 months or through the end of RSV season (March 31), whichever comes first.

Specialized Nutritionals - Approval may be given for up to 12 months.

Antidepressants - Approval may be given for up to 12 months.

Narcotic Analgesic - Approval may be given for up to 3 months with initial and renewal requests unless one of the qualifying diagnoses is indicated, then approval may be given for up to 6 months.

Platelet Aggregation Inhibitors – Approval may be given for up to 12 months for TIA Management if TIA occurs while on aspirin. For Acute Coronary Syndrome and Coronary Revascularization Procedures, approval will only be given for up to 12 months from the date of the event.

Skeletal Muscle Relaxants – Approval may be given for up to 6 months initially and up to12 months for renewal requests for chronic conditions with muscle spasticity. For acute conditions approval may be granted for up to a 10-day course of medication consistent with current maximum limits when criteria are met.

Anxiolytics, Sedatives and Hypnotics – Approval may be given for up to 3 months initially and up to 6 months for renewal requests**.**

Xolair® – Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

Antihyperlipidemics - Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

Agents for ADD/ADHD - Approval may be given for up to 12 months.

Antihypertensives – Approval may be given for up to 12 months.

Estrogens - Approval may be given for up to 12 months.

Triptans - Approval may be given for up to 6 months initially and up to 12 months for renewal requests**.**

Respiratory Agents – Approval may be given for up to 12 months.

Cardiac Agents – Approval may be given for up to 12 months.

EENT Antiallergic Agents-Approval may be given for up to 12 months.

EENT Vasoconstrictor Agents-Approval may be given for up to 12 months.

Intranasal Corticosteroids – Approval may be given for up to 12 months.

Alzheimer's Agents - Approval may be given for up to 12 months.

Antidiabetic Agents - Approval may be given for up to 12 months.

Skin and Mucous Membrane Agents - Approval may be given for up to 12 months.

Anti-infectives – Approval may be given for up to 12 months.

Section Two: Patient Information

- Record the patient's name as it appears on their Medicaid card, and their Medicaid number.
- Record patient's date of birth.
- Fill in the patient's phone number with area code.
- Indicate whether the patient is a nursing home resident.

Section Three: Prescriber Information

- Record the prescribing practitioner's name and license number, along with phone number and fax number with area codes. Mailing address is optional
- The prescriber should sign and date in this section on the prescribing practitioner signature line. By signing in the space indicated the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.

Section Four: Dispensing Pharmacy Information

- Information in this area may be completed by the pharmacy.
- Enter the pharmacy name and provider number.
- Enter phone number and fax number with area code.
- Record the NDC number.

Section Five: Drug/Clinical Information

- **This information is required for all requests.**
- Record the name of the drug and the strength requested.
- Enter the J code if the drug requested is to be administered using office medications.
- Enter the quantity of the drug requested per month.
- Circle the number of refills requested.
- Record diagnosis(es) that justifies the drug requested. Diagnosis(es) **or** ICD-9 code(s) may be used. Use of ICD-9 codes provides specificity and legibility and will usually expedite review.
- Indicate whether this is a first request or renewal request.
- Explain the reason this drug is required, and attach any additional medical justification necessary. Medical justification is documentation to support the physician's choice of the

requested course of treatment. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) illustrates and supports the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or a history of allergy to a first-line drug, and the physician wants to order a non-preferred drug, documentation from the patient record would support that decision.

Section Six: Drug Specific Information

ADD/ADHD Agents/Alzheimer Agents/ Anxiolytic, Sedative and Hypnotic Agents/ Antidepressant Agents/ Antidiabetic Agents/ Antihistamine Agents Antihyperlipidemic Agents/ Antihypertensives Agents/ Anti-infective Agents/ Cardiac Agents/ EENT Antiallergic Agents/ EENT Vasoconstrictor Agents/ Estrogen Agents/ H2 Antagonist Agents/ Intranasal Corticosteroids Agents/ Narcotic Analgesic Agents/ NSAID Agents/ Platelet Aggregation Inhibitor Agents/ PPI Agents/ Respiratory Agents/ Skeletal Muscle Relaxants/ Skin and Mucous Membrane Agents/ Triptans

- Prior authorization requires that two (2) prescribed generic, OTC or brand name drugs have been utilized unsuccessfully relative to efficacy and/or safety within six (6) months prior to requesting the PA. The PA request must indicate that two (2) generic, OTC or other brand drugs have been utilized for a period of at least thirty (30) days each (14 days for EENT Antiallergic Agents or Triptans; 3 days for EENT Vasoconstrictor Agents), **unless** there is an adverse/allergic response or contraindication. If the prescribing practitioner feels there is a medical reason for which the patient should not be on a generic, OTC or brand drug or drug trial, medical justification may be submitted in lieu of previous drug therapy.
- Check the applicable drug classification requested. For H2 antagonists and PPIs note whether this request is for **acute** or **maintenance therapy.**
- List previous drugs that were used unsuccessfully (generic, over the counter (OTC) or brand drugs) and the reason that each drug was discontinued. **If there were no failed trials with other drugs, additional medical justification must be provided to justify the request.**
- For those classes in which "stable therapy" is allowed if the patient has been stable (same drug, same strength) on requested drug for the timeframe specified in the specific drug class, medications provided through a government or state sponsored drug assistance program for uninsured patients may be counted toward the stable therapy requirement. Providers will be required to document this information on the PA request form and note the program though which the medication was dispensed. Medications paid for through insurance, private pay or Medicaid are also counted toward the requirement.
- If the drug requested is a "less-sedating" or "second generation" **Antihistamine**, prior usage requirements apply.
- If the drug requested is an **Antidepressant,** medical justification may be submitted in lieu of prior usage requirements. Acceptable medical justification may consist of the indication of "stable therapy" providing the original start date of the requested medication is provided with an indication of why the specific brand requested is medically necessary, documentation of allergies or contraindications to all preferred agents or significant past history of depression containing information related to the specific episode(s) i.e. past hospitalization for depression, suicidal attempt,

or counseling with concomitant depression. "Stable therapy" will only be accepted for initial PA requests when documentation is provided of paid prescriptions of at least 60-days or greater consecutive therapy for the medication requested. Documentation must be provided in the Medical Justification area of the PA form and required attachments provided of the source of medication. Examples include "Patient received 120 days of Name of Requested Medication from Name of third party payor and documentation from the pharmacy is attached" or "Patient had no pharmacy coverage and paid for the medication and documentation from the pharmacy is attached." For combination therapy antidepressant products, the patient needs to have appropriate diagnoses supported by documentation in the patient record.

- If the drug requested is a **COX II,** please submit medical justification, which should include the relevant diagnosis, any additional diagnoses, and any history preventing the use of other NSAIDs.
- If the drug is an **H2 Antagonist,** approval may be given without failed drug trials **if** a relevant diagnosis and documentation of testing with date and results are provided.
- If the drug requested is a **PPI** and there were no failed trials with preferred agents in this class and lifestyle modifications, medical justification must be submitted documenting testing with date and results. Lifestyle modifications include elevation of the head of the bed (on 6-inch blocks or foam wedge), avoiding lying down within 3 hours after meals, avoiding acidic foods (tomato products, citrus fruits, spicy foods, coffee) and agents that relax the lower esophageal sphincter or delay gastric emptying time (fatty foods, peppermint, chocolate, alcohol, smoking), weight loss, avoidance of bending after meals, and reduction of meal size. Additional medical justification for consideration for approval outside criteria may be attached, including medical justification for the absence of lifestyle modifications in nursing home patients. For PPIs, medical justification need is diagnosis driven and outlined as follows:

  GERD

  For **mild to moderate GERD (Grade I, II, or III)**, medical justification documentation **must** indicate lifestyle modifications implemented and failure of preferred agents in this class prescribed for at least 8 weeks with persistence of symptoms. Testing is not required for acute therapy with moderate to severe symptoms, defined as $\geq$ 2 episodes/week of nocturnal heartburn, and $\geq$ 3 episodes/week of daytime heartburn or indigestion, with no resolution or worsening of symptoms. Approval may be given for up to 4 weeks of **acute** therapy. If moderate to severe symptoms persist and there is documentation in the medical record of compliance with lifestyle modifications an additional 8 weeks of treatment may be approved without testing. If symptoms persist, documentation of appropriate testing (barium contrast or double contrast radiography, or endoscopy) with results is required for approval of additional **maintenance** therapy.

  For **severe GERD (Grade IV or V)**, diagnosis must be confirmed by testing (barium contrast or double contrast radiography, or endoscopy) within the past 12 months. For acute therapy the patient may be approved for up to 8 weeks of therapy. If severe GERD symptoms continue or do not resolve **and** there is documentation of recommended

lifestyle modifications, approval for **maintenance** therapy may be given for an additional 12 weeks of treatment.

Positive H. pylori

If the patient has tested positive for H. pylori (breath test, blood test or tissue biopsy if endoscopic exam done) and met prior usage requirements, approval may be given for up to 2 weeks of combination therapy. Requests for Prevpac should meet Prevpac criteria, not PPI criteria.

Gastric ulcer, duodenal ulcer, or esophagitis

The patient must have an appropriate diagnosis confirmed by testing (barium contrast or double contrast radiography, or endoscopy) within the past 12 months and meet prior usage requirements. If these requirements are met, up to 8 weeks of **acute** therapy may be approved. If on completion of 8 weeks of acute treatment for esophagitis (erosive or non-erosive) symptoms persist, approval may be given for up to 6 months of maintenance treatment. After 12 months, approval will require documentation of persistent symptoms and the results of retesting.

Hypersecretory Conditions

If the patient is diagnosed with Barrett's Esophagitis, Zollinger-Ellison, or other hypersecretory disorders, which have been confirmed by testing (barium contrast or double contrast radiography, or endoscopy), then approval of up to 12 months of **acute** treatment may be issued, with continued **maintenance** therapy approved in 12 month increments. Renewal requests do not require retesting but do need documentation of persistence of symptoms.

For **Prevacid NapraPac™** the patient must have a diagnosis of gastric ulcer, diagnosed within the past 12 months, **and** require the use of an NSAID for treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, or ankylosing spondylitis. The patient must also have failed two 30 day treatment trials with at least two prescribed NSAIDs while on concomitant H2 or PPI therapy within the past 6 months, either generic, OTC or brand, or have a documented contraindication to all preferred agents in this class.

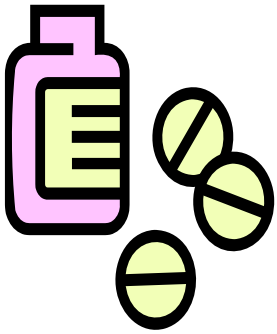
For **Prevpac®** the patient must have a diagnosis of duodenal ulcer, confirmed by testing within the past 12 months, and must also test positive for H pylori, confirmed by testing within the past 30 days. The patient must have failed two acute treatment trials of at least 14 days each with lack of healing on an acid suppressor and antibiotics, either generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in these classes.

- If the drug requested is a **Narcotic Analgesic,** medical justification may be submitted in lieu of prior usage requirements and may consist of diagnosis and ICD-9 codes, documentation of therapeutic pain management failure with NSAIDs, APAP, or ASA and must consist of a complete pain evaluation in the medical record. Type of pain (acute versus chronic) and pain intensity (mild, moderate or severe) must be indicated in the Drug/Clinical Information section, Medical Justification. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.

- If the drug requested is a **Platelet Aggregation Inhibitor,** medical justification may be submitted in lieu of prior usage requirements. Acceptable medical justification may consist of clinical diagnoses indicating 1st line treatment by certain branded products in lieu of ASA, documentation of contraindication or intolerance to the use of ASA, ticlopidine and dipyridamole. Clinical literature reviewed supports the use of certain branded products for specific indications; Plavix® (Clopidogrel) and Aggrenox® (ASA/DP-ER) are indicated for **TIA Management if TIA occurs while on ASA**. Plavix® (Clopidogrel) is indicated as an adjunct to ASA in **some Coronary Revascularization Procedures (ex: percutaneous coronary intervention)** or in patients with **Acute Coronary Syndrome**. The dates of these events must be included in the medical justification section of the Prior Authorization form. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is a **Skeletal Muscle Relaxant** and the patient has not failed 30 day trials with two (2) prescribed generic, OTC or brand skeletal muscle relaxants, approval may be given if the patient has been on consecutive 60 day or greater treatment with the skeletal muscle relaxant being requested for a **chronic** condition associated with muscle spasticity. The request may also be approved for an acute pain or musculoskeletal condition with documented allergy or contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is an **Anxiolytic, Sedative or Hypnotic** the patient must have documentation of prior usage requirements or contraindications to all preferred agents in this class for approval. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is an **Antihyperlipidemic** the patient must have had failed 30 day trials with at least two prescribed lipid lowering agents, either generic, OTC or brand, and lifestyle modifications within the past 6 months, unless there is a contraindication to all preferred agents in this class. Lifestyle modifications include weight loss, dietary changes and establishment of a physical exercise regimen. If prior usage requirements have not been met, approval may be obtained for adjunctive therapy to a current lipid lowering drug. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the request is for a **CNS Stimulant** or other agent to treat ADD/ADHD approval may be given if the request includes a valid diagnosis. The patient must have failed two 30-day treatment trials with prescribed CNS stimulants or other drugs to treat ADD/ADHD, either generic or brand, along with alternative therapies within the past 6 months, unless there is a contraindication to all preferred agents in this class, or valid medical justification is attached. If the patient has

not failed previous therapies, they must have been stable on consecutive 60 day or greater treatment with the ADD/ADHD drug requested. Acceptable medical justification may consist of the indication of "stable therapy" providing the original start date of the requested medication is provided with an indication of why the specific brand requested is medically necessary. Acceptable examples of alternative therapies include counseling, behavior modification, documentation of consultation from a psychiatrist or prescription by a psychiatrist with documentation explaining why a preferred drug is inappropriate. This information must be included in the "Medical Justification" area of the form when checked.

- If the drug is an **Antihypertensive** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must have failed 30 day treatment trials with at least two prescribed antihypertensive agents, generic, OTC or brand, and lifestyle modifications or have a documented contraindication to all preferred agents in this class. To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). For example, to qualify for a non-preferred beta blocker, the patient must have met prior usage requirements of 30 day treatment trials with two other preferred beta blockers, either generic, OTC or brand. Lifestyle modifications include weight loss, dietary modifications and establishment of a physical exercise regimen. "Stable therapy" will only be accepted for PA requests when documentation is provided of paid prescriptions of at least 60-days or greater consecutive therapy for the medication requested. Documentation must be provided in the Medical Justification area of the PA form and required attachments provided of the source of medication. Examples include "Patient received 120 days of Name of Requested Medication from Name of third party payor and documentation from the pharmacy is attached" or "Patient had no pharmacy coverage and paid for the medication and documentation from the pharmacy is attached."
- If the drug is an **Estrogen** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with two other prescribed agents in this class within the past 6 months, either generic, OTC or brand, or have a documented contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.



- If the drug is a **Triptan** the patient must have an appropriate diagnosis supported by documentation in the patient record and the request must be for acute treatment, not prophylactic therapy. The patient must also have failed 2 week treatment trials with two other prescribed Triptans, either generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in this class. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is a **Respiratory Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with at least two other prescribed respiratory agents in this class, either

generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in this class. Requests for Pulmicort Respules™ or Singulair® will not require failed therapy for children under age five with diagnosis of asthma. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.

- If the drug is a **Cardiac Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with at least two other prescribed cardiac agents in this class, either generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in this class. To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). For example, to qualify for a non-preferred cardiotonic, the patient must have met prior usage requirements of 30 day treatment trials with two other preferred cardiotonic agents, either generic, OTC or brand. "Stable therapy" will only be accepted for initial PA requests when documentation is provided of paid prescriptions of at least 60-days or greater consecutive therapy for the medication requested. Documentation must be provided in the Medical Justification area of the PA form and required attachments provided of the source of medication. Examples include "Patient received 120 days of Name of Requested Medication from Name of third party payor and documentation from the pharmacy is attached" or "Patient had no pharmacy coverage and paid for the medication and documentation from the pharmacy is attached."
- If the drug is an **EENT Antiallergic Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. For ophthalmic products, the patient must also have failed 14 day treatment trials with at least two other prescribed and preferred ophthalmic agents in this class, either generic, OTC or brand, within the past 12 months or have a documented contraindication to all preferred agents in this class. For nasal products, in addition to documentation of an appropriate diagnosis, the patient must have failed 14 day treatment trials with at least two antiallergic agents, to include oral antihistamines, intranasal corticosteroids or intranasal cromolyn, either generic, OTC or brand within the past 12 months. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is an **EENT Vasoconstrictor Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 3 day treatment trials with at least two other prescribed and preferred agents in this class, either generic, OTC or brand, within the past 6 months. Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is an **Intranasal Corticosteroid** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with at least two other prescribed intranasal corticosteroids in this class, either generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in this class. Approval may be given for children age

18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.

- If the drug is an **Alzheimer's Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with at least one other prescribed Alzheimer's agent in this class, either generic, OTC or brand, within the past 6 months, have a documented contraindication to all preferred agents in this class, or have been on consecutive 90-day or greater treatment with the agent requested. Stable therapy for this class is defined as a 90- day or longer timeframe on the same medication, same strength and is to allow for approval of patients who have been determined to be stable on the medication. Documentation to support stable therapy must be provided in the Medical Justification area of the PA form with required attachments provided of the source of medication.

- If the drug is an **Antidiabetic Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with at least two other prescribed diabetic agents in this class, either generic, OTC or brand, within the past 6 months, have a documented contraindication to all preferred agents in this class, or have been on consecutive 60-day or greater treatment with the agent requested. Documentation must be provided of the source of the medication which meets stable therapy requirements. Examples include "Patient received X days of Name of medication from Name of third party payor and documentation from pharmacy is attached" or "Patient had no pharmacy coverage and paid for the medication and documentation from pharmacy is attached". Documentation to support stable therapy must be provided in the Medical Justification area of the PA form with required attachments provided.
- If the drug is a **Skin and Mucous Membrane Agent** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed 30 day treatment trials with at least two other prescribed skin and mucous membrane agents in the class, or one when appropriate based on PDL preferred agents, either generic, OTC or brand, within the past 6 months, have a documented contraindication to all preferred agents in this class or have sufficient medical justification for approval in lieu of treatment trials for branded drugs where there is no preferred, generic or OTC alternative. To meet prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater. The original start date of the requested medication must be provided with an indication of why the specific brand requested is medically necessary.
- If the drug is an **Anti-infective** the patient must have an appropriate diagnosis supported by documentation in the patient record. The patient must also have failed two treatment trials of no less than a three day trial each, with other preferred and prescribed anti-infectives, either generic, OTC or brand, within the past 30 days or have a documented contraindication to all preferred agents in this class. Patients on anti-infective therapy while institutionalized once discharged or transferred to another setting or patients having a 60 day consecutive stable therapy may continue on that therapy with supportive medical justification. Approval may

also be given, with medical justification, if the medication requested is indicated for first line therapy when there are no other indicated preferred agents available or if indicated by susceptibility testing or evidence of resistance to all preferred agents. Medical justification may be provided in the appropriate area on the request form or included as an attachment.

Sustained Release Oral Opioid Agonist

- Approval may be given for the treatment of intractable, chronic pain with oral SR opioid agonists (OxyContin®, Kadian®, Oramorph SR®, MS Contin®, Avinza™). These medications are narcotic analgesics and Schedule II controlled substances. They are not intended for use with acute pain, as a PRN analgesic or for short-term pain management (≤ 10 days). The patient must have had failed 30 day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance opioid analgesia, unless the primary diagnosis is an approved cancer diagnosis. Submission of a plan of action addressing continued medical monitoring, titration and a written signed contract for therapy is required for patients with a history of substance abuse or addiction, unless the patient is a nursing home resident. For nursing home residents with a history of substance abuse or addiction, medical justification may be submitted in lieu of a plan of action, alternate pain management choices and adjuvant therapy. For patients ≥ 65 years of age, medical justification may be provided in lieu of non-opioid adjuvant drugs.
- Indicate how long patient will require treatment with Sustained Release Opioid Agonists (SROAs).
- You must indicate whether drug is intended for PRN use. **SROAs are not for short-term pain management (≤ 10 days) or for PRN use.**
- Indicate the type of pain and severity. **SROAs are not intended for use with acute pain.**
- Indicate prior and/or current analgesic drugs used and alternative management choices. **The patient must have had failed 30 day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance analgesia, unless the patient has an approved cancer diagnosis.**
- Indicate whether the patient has a history of substance abuse or addiction. **If the answer is yes, a treatment plan (a plan of action addressing continuing medical monitoring, titration, and a written signed contract for therapy) must be attached to the request, unless the patient is a nursing home resident.**

Xolair®

- Prior authorization for treatment with Xolair requires that the patient's course of treatment be recommended by a board certified pulmonologist or a board certified allergist.
- The patient must be 12 years of age or older.
- The patient must be symptomatic despite receiving a combination of either inhaled corticosteroid and leukotriene inhibitor **or** an inhaled corticosteroid and a long acting beta agonist **or** the patient must have required 3 or more bursts of oral steroids within the past 12 months.
- The patient must have had a positive skin or blood test reaction to a perennial aeroallergen.

- Appropriate IgE to mass ratios must be followed, with the baseline IgE levels between 30 IU/ml and 700 IU/ml.
- The patient must weigh between 30kg and 150 kg.

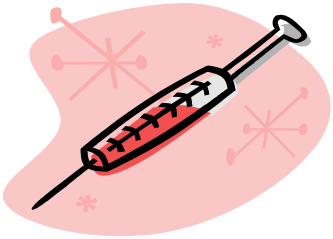
Biological Injectables

- Check the applicable drug.

A. Remicade® (Infliximab)

Rheumatoid Arthritis

For prior authorization the patient must have a diagnosis of rheumatoid arthritis [diagnosis of rheumatoid arthritis or other rheumatoid arthritis with visceral or systemic involvement, or polyarticular juvenile rheumatoid arthritis] that has been confirmed by a board certified rheumatologist. The patient must also have a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), at least one of which is Methotrexate, unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathriprine, oral gold, intra-muscular gold. The patient will need to continue on methotrexate in conjunction with Remicade therapy, unless there is a contraindication to its use. Any contraindications or intolerance to methotrexate use will need to be identified with appropriate supportive documentation included.



Crohn's Disease

For prior authorization the patient must have a diagnosis of moderately to severely active Crohn's disease [diagnosis of regional enteritis (Crohn's disease or granulomatous enteritis) of the small intestine, large intestine, small intestine with large intestine, and/or unspecified site, anal fistula and/or fistula of the intestine, excluding rectum and anus] that has been confirmed by a board certified gastroenterologist. To be approved, the patient must have had an inadequate response (persistence of significant and/or progressive weight loss, fevers, abdominal pain or tenderness, intermittent nausea or vomiting and/or significant anemia or increase or lack of reduction in the number of draining enterocutaneous fistulae in patients with fistulizing Crohn's disease) to one or more conventional therapies, which include aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, ciprofloxin, cyclosporin.

B. Enbrel® (Etanercept)

For prior authorization the patient must have a diagnosis of rheumatoid arthritis, polyarticular juvenile rheumatoid arthritis, psoriatic arthritis or active ankylosing spondylitis or plaque psoriasis. Submitted documentation must include evidence that the course of treatment with Enbrel® is recommended by a board certified rheumatologist or dermatologist.The patient must also have failed a 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

C. Kineret® (Anakinra)

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include a diagnosis of rheumatoid

arthritis, confirmation of drug therapy by a board certified rheumatologist, and a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

D. Humira™ (Adalimumab)

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include confirmation by a board certified rheumatologist. The patient must also fail a 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

E. Orencia® (Abatacept)

For prior authorization the patient must have a diagnosis of moderately to severely active rheumatoid arthritis. Submitted documentation must include a diagnosis of rheumatoid arthritis, confirmation of drug therapy by a board certified rheumatologist, and a failed 30 day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use.

F. Raptiva™

Raptiva is indicated for the treatment of chronic moderate to severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy or phototherapy. The patient must have had a failed 6 month trial with topical treatment(s), either generic, OTC or brand, within the last year or documentation of contraindication to all agents in this class. Patients may be taught to self inject, under the guidance and supervision of a physician. Granting of further approvals is dependent on patient compliance**.**

G. Amevive®

Amevive is indicated for the treatment of chronic moderate to severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy or phototherapy.The patient must have had a failed 6 month trial with topical treatment(s), generic OTC or brand, within the last year or documentation of contraindication to all agents in this class.

Xenical®

- To receive prior authorization for Xenical®, the patient must be 18 years of age or older and have at least one of the following primary medical diagnoses: Diabetes Mellitus, Hypertension, or Hyperlipidemia.
- For initial requests the patient's height (in inches), weight (in pounds) and BMI are required.
- Renewal requests require the patient's previous and current weights (in pounds). **Continued weight loss must be documented for renewals.**

- There must be documentation in the patient record to support failure with prior physician supervised exercise/diet regimen(s) of at least 6 months duration. Documentation must also show that adjuvant therapy is planned.
- Dosage requested must not exceed 120 mg TID.

Erectile Dysfunction Drugs

- Phosphodiesterase inhibitors require diagnosis of severe pulmonary hypertension (defined as systolic pulmonary pressure > 80mm HG as determined by cardiac catherization) with documentation of failure of or contraindication to all other available therapies. Documentation must be provided of vasoreactivity testing and consultation with a specialist experienced in the treatment of pulmonary hypertension patients.
- A sole diagnosis of impotence will not be approved.

Synagis®

- Synagis® has been approved by Alabama Medicaid for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk for RSV disease. The patient must meet the gestational age, age at request requirements, and must be an outpatient with no in-patient stay for at least two weeks prior to the date of the medication request. Infants less than six (6) months old with gestational age of 33-35 weeks may qualify with 2 or more of the AAP risk factors (child care attendance, school-age siblings, congenital abnormalities, severe neuromuscular disease, and exposure to environmental air pollutants).
- Environmental air pollutants do not include second-hand smoke. Environmental air pollutants would include instances where a child is **constantly** exposed to particulate air matter and should be described in detail in the Drug/Clinical information section of the PA form.
- Additional medical justification for high-risk toddlers less than twenty four (24) months of age may be given for hemodynamically significant CHD (Congenital Heart Disease) or CLD (Chronic Lung Disease) with documentation provided as defined. For CLD, documentation must support gestational age less than or equal to 35 weeks with parenchymal disease resulting from oxygen or ventilator support and ongoing medical intervention throughout the RSV season consisting of supplemental O2, bronchodilators, oral steroids, inhaled steroids, or diuretics. For hemodynamically significant CHD, the patient must be less than 24 months of age and documentation must show ongoing treatment consisting of home use of supplemental daily oxygen, diuretics, or other medications to control congestive heart failure, moderate to severe pulmonary artery hypertension or cyanotic congenital heart disease, and no surgical correction of cardiac defect.

- Patients who have received prior authorization should receive monthly doses (up to 5 doses) throughout the RSV season as defined by the Alabama Medicaid Agency. RSV prophylaxis approval will terminate after March 31.
- Current weight is required.
- In addition to the above, the patient must also be an out patient with no inpatient stay within the past 2 weeks.
- Check appropriate category for age, condition, and risk factors.

- Approval authorizes only one (1) dose (based on patient weight) every thirty days up to a five (5) dose maximum or through March 31. The season will begin no earlier than October 1. **No request for more than five (5) doses will be approved. No dose may be given after March 31, and requests for more than one dose in a thirty-day period cannot be approved.**
- **Medical documentation acceptable for Synagis® prior authorization must include all medications, frequency of medication dosing, and diagnosis(es) with indications of severity of illness. A periodic review of medical records will be conducted by the Alabama Medicaid Agency or designees.**

Specialized Nutritional

- Patients who, because of illness or trauma, cannot be sustained through oral feedings and must rely on enteral nutrition therapy may qualify for coverage under Medicaid. Enteral nutrition may be administered by nasogastric, jejunostomy, or gastrostomy tubes.
- Specialized nutrition is covered for Medicaid eligible EPSDT recipients less than 21 years of age with nutritional disorders. They do not have to be tube fed, but the specialized feeding must constitute more than 50% of their nutritional needs. A qualifying diagnosis is required.
- Recipients age 21 and over who must rely on enteral feedings as their only source of nutrition may qualify for Medicaid coverage if they have a qualifying diagnosis and meet disease specific criteria.
- Current height and weight are required.
- Select appropriate age category.
- Indicate how specialized nutritional is administered, along with the duration and number of refills.

- Prior authorization is for the nutritional product only and does not include any equipment or supplies necessary to administer the nutrients. Supplies and equipment used in conjunction with nutritional therapy may be covered in the Medical Supplies, Appliances and Durable Medical Equipment Program. For more information on supplies and equipment, see Chapter 14 of the Medicaid Provider Manual or contact Medicaid Provider/Recipient Services at 1-334-293-5504.

Section Seven: Exempted Drugs

Currently only antipsychotics and HIV/AIDS drugs are exempted from the mandatory preferred drug list and new prior authorization requirements.

Section Eight: Frequently Asked Questions

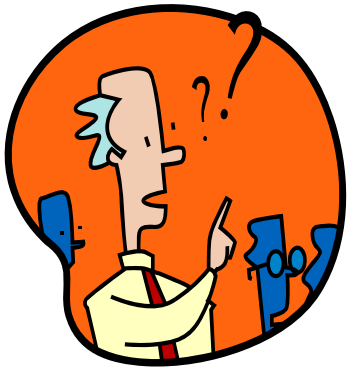
1. What is difference between the new PDL and the old PDL?

- Medicaid is implementing a **mandatory** Preferred Drug List. The previous PDL was voluntary and for educational purposed only.
- Preferred drugs are products that have been evaluated as to safety, efficacy and therapeutic value. They are, within their classes or categories, therapeutically equivalent and effective.

2. **How will this affect my practice?**
   - Brand drugs within the scope of the PDL but not on the preferred drug list will require prior authorization.
   - Prescriptions that are written for brand preferred drugs, generic and over-the-counter drugs will not require prior authorization.

3. **What drugs will be on the Preferred Drug List?**
   - Generic and over-the-counter drugs covered by Medicaid will be preferred agents. Additionally, certain brand name drugs will be preferred agents.
   - HIV/AIDS drugs and antipsychotics are excluded from the list so prior authorization is NOT necessary for these categories.

4. **Who determines which drugs are on the Preferred Drug List?**
   - Medicaid will utilize a Pharmacy and Therapeutics Committee (P&T) Committee to develop a Preferred Drug List based on clinical efficacy, safety, and patient care factors.
   - The P&T Committee is comprised of at least 5 practicing physicians nominated by the Medical Association of the State of Alabama and 3 clinical pharmacists nominated by the Alabama Pharmacy Association.
   - Members of the P&T Committee represent various fields of specialty including psychiatry, internal medicine, pediatrics, long-term care, and independent pharmacy.



5. **Will this keep my patients from getting the drugs they need?**
   - No, reasonable responses to prior authorization requests are available and an automatic approval mechanism is in place for a 72 hour emergency supply.
   - The plan will be driven by patients' medical needs, provide for prompt decision making, include a fair appeals process for patients and providers and be minimally burdensome to prescribers.
   - Patients will not be placed in jeopardy because the Preferred Drug List will be based on clinical effectiveness above all other considerations.
   - Prior authorization of medications that are non-preferred drugs does not prevent patients from receiving the medication. A physician may request a prior approval for non-preferred drugs.

6. **When will the changes be implemented?**
   - The list will be implemented in phases.
   - The first set of drugs will begin on October 1, 2003 and be phased in over a period of approximately 6 months.

7. **Are drug costs ever a factor in determining what goes on the preferred list?**
   - Clinical issues such as efficacy and side effects are primary considerations in determining which drugs are preferred. The P & T Committee does not have cost information when

they review clinical information and make their recommendation. Cost information may be considered by Medicaid if, and only if, the P & T Committee determines drugs within a class are equally safe and effective.

8. Are original prescriptions and signatures required for all drugs?

- Medicaid requires original, signed prescriptions for Schedule II drugs and Brand Medically Necessary drugs.
- Schedule III, IV, and V drugs may be called in, as allowed by state pharmacy regulation.

9. Can a call-in prescription be accepted for a MAC drug when brand necessary certification is required?

- No. The MAC price may only be waived when a pharmacy has a prescription with "Brand Medically Necessary" written in the prescribing physician's own handwriting. Therefore, having a written prescription is necessary. For example, because Zantac is a MAC drug and requires brand medically necessary certification on the prescription, a telephone prescription would not be acceptable in order to receive brand reimbursement.

10. Can I make a therapeutic or strength substitution without calling the prescribing physician?

- No. Alabama State law requires the pharmacist to have the approval of the prescribing physician before dispensing anything other than what has been indicated on the prescription.
- If the physician has indicated product selection is allowed, the pharmacist may dispense generic substitution without subsequent contact with the physician.

11. What is the appropriate action when a physician writes a prescription that exceeds the Medicaid monthly dosing units?

- When a prescription is denied for excessive quantity or monthly limit exceeded, claims will deny. In order to receive an override, providers (either the pharmacy or physician) should contact the HID help desk (1-800-748-0130) for consideration of an override.

12. How long is a prescription valid?

- In accordance with state law, controlled substance prescriptions are valid for up to six (6) months from the original issue date.
- Non-controlled prescriptions are reimbursable by Medicaid for up to twelve (12) months from the date of the original dispensing date.

13. Can I receive authorization for additional refills from the prescribing practitioner after twelve (12) months have expired?

- No. A new prescription should be obtained after twelve (12) months from the date of the original dispensing date.
- Medicaid will make payment for up to 5 refills on an original prescription. The pharmacist should not request additional refills from the physician.

14. Why is it important that I bill the exact NDC number dispensed if the product is a generic?

- According to Jerry Moore, State Board of Pharmacy, pharmacies dispensing controlled substances and submitting claims with different NDC numbers will have problems with the Drug Enforcement Agency (DEA). Additionally, Medicaid provider contracts require that claims be submitted accurately. Under federal law, manufacturers rebate Medicaid for use of their drugs. When an NDC is submitted on a claim that is not the actual NDC dispensed, Medicaid may incorrectly invoice the manufacturer for the rebate. Rebate dollars provide a significant source of money to offset pharmacy benefit costs. Therefore, NDC numbers reported on pharmacy claims should be the exact NDC number dispensed to the patient.

15. Can referrals be made to Medicaid when a provider believes a recipient is defrauding the program?

- Yes. Information about possible illegal drug-related activity, abuse, misuse or fraud by Medicaid recipients can be referred to 1-800-362-1504.
- All complaints are researched. If evidence is found to support recipient abuse or fraud, recipients can be locked in to one physician and one pharmacy, removed from the Medicaid program, or referred to the District Attorney.

16. Does Medicaid make payment for benefits when a patient is in a state or county correctional facility?

- After a recipient has been convicted and is incarcerated, the recipient may no longer receive Medicaid benefits. It is the responsibility of the correctional facility to provide medical care.
- Youth in the custody of the Department of Youth Services (indicated by County Code 69) may be eligible for Medicaid coverage. Providers should continue to verify eligibility prior to dispensing medications.
- For additional information regarding incarcerated recipients and Medicaid coverage, call 1-800-362-1504.

17. If a provider receives multiple dispensing fees for the same patient, same drug and strength within the same month, will the additional dispensing fees be recouped?

- Medicaid auditors look specifically for providers who split 30-day prescriptions into shorter time periods and amounts. Intentionally splitting prescriptions to receive multiple dispensing fees is fraud, monies paid will be recouped, and appropriate referrals may be made to the Attorney General's office.
- Multiple dispensing fees within the same month for the same patient and same drug are acceptable if the provider has documentation supporting the need for multiple dispensings. Example: A provider writes a 30 day prescription for a medication and there is only 7 days of medication in the pharmacy. The patient is given the 7 day supply and a dispensing fee is charged. When the patient returns for the rest of the prescription, the pharmacist can not charge for a second dispensing fee.

18. If a provider is audited and can not produce documentation while Medicaid auditors are in the store, is there a period of time allowed to provide the documentation before recoupments are initiated?

- If an auditor requests documentation that is not present in the provider's facility, the provider should indicate to the auditor where the documentation is and when it can be provided for review.
- If additional information is needed by the state as a result of discrepancies identified in an audit, the provider should submit the requested information within 30 days of the request. Failure to submit documentation within 30 days may result in recoupment and additional action as necessary.