Alabama Medicaid
Pharmacy Override

Therapeutic Duplication, Ingredient Duplication, Early Refill, Maximum Unit, Prescription Limit Switchover, Dispense as Written, Accumulation Edit, Maintenance Supply Opt Out, Maximum Cost, and Short Acting Opioid Naïve Override Criteria Instructions

Alabama Medicaid provides reimbursement for covered outpatient pharmacy drugs based on a 34-day supply. Some maintenance classes are required to be billed as a three-month supply. Medicaid recognizes that there are certain situations when a pharmacist will receive a hard denial in the system such as: Early Refill, Therapeutic Duplication, Ingredient Duplication, Excessive Quantity, Maximum Cost, Prescription Limitation Exceeded, Patient has Reserve Medication, Maintenance Supply Required, Short Acting Opioid Naïve Patient, and Dispense as Written. For the pharmacist to receive reimbursement, an override must be approved by Keystone Peer Review Organization, LLC. Requests can be made by the pharmacist, physician or their authorized representative unless otherwise indicated below. Override requests for Short Acting Opioid Naïve patients will be submitted on a separate form. Override requests for outpatient gene therapy agents will be submitted on a separate form (see section F- Maximum Cost). The following Pharmacy Override Instructions may be used as a guide to providers submitting an override request.

Section One
Override Form: General Information

A. Therapeutic Duplication

Therapeutic duplication is the prescribing of two or more drugs from the same therapeutic class such that the combined daily dose increases the risk of toxicity or incurs additional program costs without additional therapeutic benefit. This edit will warn pharmacists when a claim is submitted for a systemically absorbed drug in the same therapeutic class or a non-systemically absorbed drug with the same route of administration as another drug in the patient's active medication history. This edit takes into consideration the exhaustion of previously dispensed medications by calculating the day's supply and the dispensed date.

Providers may request an override if one of the following reasons for the request is indicated. The reasons and documentation requirements for approval of requests for override of the therapeutic duplication edit are as follows.

1. **Strength Change/Dosage Change:** The request may be approved when a different strength of the same medication is required, either a higher or lower strength, with a valid, medically necessary reason for change provided (e.g., initial dose too strong, initial dose not strong enough, B/P too low on initial dose, higher dose needed, lower dose needed, etc.). This request can be initiated by the pharmacist, physician, or their authorized representative based on information available from previous medications filled or from information available on the new prescription. The stop date of the medication being changed or discontinued and reason for the change must be provided. The override request can be made verbally and does not require the physician to sign the Pharmacy Override Form.

2. **Switch Over:** This request indicates that a medication change is medically necessary within the same class. The reason for the change must be included when the request is made. The stop date of the medication being discontinued must be provided as well as the NDC number for the drug being requested. The override request can be made verbally and does not require the physician to sign the Pharmacy Override Form.

3. **Titrations/Concomitant Therapy:** This request is used when the request is for medications within the same class being titrated (initial medication titrated down while second medication is being titrated up) or for concomitant therapy. The name of both drugs should be included along with NDC numbers for each drug. For titration, the timeframe for discontinuation of the medication being titrated down and off should be indicated. Approval may be granted for up to 60 days, but never longer than the calculated time from request to stop date. If the titration “Stop date” is < 60 days from the request date, only the date is needed to justify the request. If the titration “Stop date” is > 60 days from the request date, additional medical justification will be required.

   If there is no indication of a “stop date” for the initial medication the request would be considered for Concomitant Therapy and supportive medical justification for this therapy must be provided. Approval may be given for up to 6 months.

B. Ingredient Duplication

Ingredient duplication is the use of the same medication in different strengths at the same time by different prescribers. The ingredient duplication edit will review claims history for possible ingredient duplication and deny claims when simultaneous use of medications containing the same active ingredient and prescribed by different prescribers are detected. The drugs to be included in the ingredient duplication edit are:

- Pregabalin (ex. Lyrica)

- Gabapentin (ex. Neurontin)

Providers may request an override if one of the following reasons for the request is indicated. The reasons and documentation requirements for approval of requests for override of the ingredient duplication edit are as follows.

1. **Strength Change/Dosage Change:** The request may be approved when a different strength of the same medication is required, either a higher or lower strength, with a valid, medically necessary reason for change provided (e.g., initial dose too strong, initial dose not strong enough, higher dose needed, lower dose needed, etc.). This request can be initiated by the pharmacist, physician, or their authorized representative based on information available from previous medications filled or from information available on the new prescription. The stop date of the medication being changed or discontinued and reason for the change must be provided. The override request can be made verbally and does not require the physician to sign the Pharmacy Override Form.

2. **Titrations/Concomitant Therapy:** This request is used when a different strength of the same medication is being titrated (initial medication titrated down while second medication is being titrated up) or for concomitant therapy. The name of both drugs should be included along with NDC numbers for each drug. For titration, the timeframe for discontinuation of the medication being titrated down and off should be indicated. Approval may be granted for up to 60 days, but never longer than the calculated time from request to stop date. If the titration "Stop date" is < 60 days from the request date, only the date is needed to justify the request. If the titration "Stop date" is > 60 days from the request date, additional medical justification will be required.

   If there is no indication of a "stop date" for the initial medication the request would be considered for Concomitant Therapy and supportive medical justification for this therapy must be provided. Approval may be given for up to 6 months.

C. Prescription Limit Switchover

If the request for a prescription limit switch over is for a prescription that exceeds the monthly limit (5 total of which 4 can be brand), the request may be approved **only** for specific drugs in the following drug classes: Antineoplastic Agents, Antiarrhythmic Agents, Cardiotonic Agents, Miscellaneous Vasodilating Agents, Miscellaneous Cardiac Agents, Nitrates and Nitrites, Alpha Adrenergic Blocking Agents, Beta Adrenergic Blocking Agents, Dihydropyridines, Miscellaneous Calcium Channel Blocking Agents, Diuretics, Potassium Sparing Diuretics, Angiotensin-Converting Enzyme Inhibitors, Angiotensin II Receptor Antagonists,

Mineralocorticoid/Aldosterone Receptor Antagonists, Central Alpha Agonists, Direct Vasodilators, Peripheral Adrenergic Inhibitors, Miscellaneous Hypotensive Agents, Hemostatics, Calcium Replacements, Electrolyte Depleters, Immunosuppresives, Alpha Glucosidase Inhibitors, Amylinomimetics, Biguanides, Dipeptidyl Peptidase-4 Inhibitors, Incretin Mimetics, Insulins, Meglitinides, Sulfonylureas, Thiazolidinediones and Miscellaneous Diabetic Agents.

Approval may be granted only for those agents specified in the classes or subclasses identified above. The request must also justify the need for switch over. If the reason given is failure to respond, specific information must be provided as to how the drug therapy failed. If the reason given is adverse or allergic reaction, the specific side effect symptoms or reaction must be indicated. If the drug requested requires PA/override, all PA/override criteria for that drug must be met for switchover approval.

D. Early Refill

Alabama Medicaid limits pharmacy prescription coverage to a 34-day supply. Some maintenance classes are required to be billed as a three-month supply. For a prescription billed for a 34-day supply or less, the prescription will be considered an early refill if 75% of the previous prescription has not been utilized. For a prescription filled for a mandatory three-month supply, the prescription will be considered an early refill if 90% of the previous prescription has not been utilized. Overrides for early refills may be approved in the event of extenuating circumstances such as medication destroyed, medication stolen, medication dosage changed, etc. Supporting documentation or medical justification (change in dosage, fire marshal's report, insurance report, police report, etc,) must be provided. If required reports are not attainable, a healthcare provider may attest to patient's need as medical justification.

Even with required documentation, stolen medications must be life sustaining to be approved. For children (under 21 years of age), requests for medications that hold abuse potential (narcotics and stimulants) must be accompanied by a police report and letter of medical necessity from the prescribing physician. For adults, requests for medications that hold abuse potential (narcotics and stimulants) will be denied. An appeal with supporting documentation may be submitted in extenuating circumstances.

E. Maximum Unit

Maximum units are based according to Food and Drug Administration (FDA) approved indications. If a patient needs a quantity greater than the current maximum units, an override request including appropriate medical justification must be submitted.

F. Maximum Cost

If a drug claim exceeds the maximum allowable cost per claim (a particular dollar amount), then an override is required. A request including diagnosis and justification of the quantity and cost of the medication being billed must be submitted. Exceptions are allowed for blood clotting factor claims. For outpatient gene therapy agents, please see Attachment A.

G. Dispense As Written

Historically, a Dispense as Written (DAW) value of "1" would allow multi-source brand name drug reimbursement to the pharmacy and would require the physician to include the words "brand medically necessary" in his/her own handwriting on the prescription prior to dispensing.

Effective May 1, 2008, an override will be required for claims for brand drugs with exact generic equivalents. Medicaid recognizes that there may be certain situations that require a brand name product to be dispensed in lieu of the generic equivalent. To be reimbursed for the brand, an override, along with a completed FDA MedWatch Form 3500, must be submitted on the Pharmacy Override PA Form. The FDA MedWatch Form 3500 can be found on the FDA website at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf as well as on the Medicaid website.

Overrides may be approved for up to 12 months. Renewals will not require an additional MedWatch form to be submitted. Exclusions to the edit include carbamazepine, levothyroxine, phenytoin, pancreatic enzymes and warfarin; overrides will not be required for reimbursement of the brand products for these drugs. For approval, the MedWatch form must include **clinical** basis for the reason the generic therapeutic equivalent is not appropriate. A physician's unwillingness to complete a form or a patient's unwillingness to take generic drugs do not constitute clinical basis. "Brand medically necessary" in the physician's handwriting is no longer be required on the prescription.

H. Accumulation Edit

On July 1, 2013, an accumulation edit was implemented to limit dispensing of early refills to no more than seven extra days' worth of medication per 120 rolling days. Claims that exceed or result in the accumulation of more than seven extra days' worth of medication in a 120-day time period will deny.

Requests for overrides of the accumulation edit may be made verbally and, if appropriate, may be approved**.** For a request to be **approved** the recipient must meet one of the following scenarios:

- Recipient has received an early refill override in the last 120 days that would account for the accumulation of the medication being requested.

- Recipient has medical justification supporting the need for additional medication. Reasons related to dose changes should be considered as early refills and processed as an early refill request.

Instances in which an override would be **denied** would include:

- Patient has medication in reserve.
- Patient has used the medication in a manner other than how prescribed.
- Pharmacy has entered an incorrect days' supply on the claim (pharmacist should be instructed to correct the history claim with an incorrect days' supply).
- Any other circumstance in which the recipient/pharmacy cannot justify why the medication is being accumulated.

I. Maintenance Supply Override

Effective October 1, 2013, Alabama Medicaid implemented a mandatory maintenance supply program. The maintenance supply program allows for dispensing of a 3-month supply of certain medications for Medicaid recipients. Once a recipient has demonstrated stability for at least 60 days (same strength and dose) on a given medication (through claims data), a 3-month supply is required.

Acceptable overrides regarding the Maintenance Supply Program include:

- Opt Out Override - Recipients that are not candidates for the maintenance supply program due to a clinical/medically justified reason may "opt out" of the program. An override request including appropriate medical justification must be submitted. Requests for opting out of the maintenance supply program **must be** signed and submitted by the prescribing physician.
- Maintenance Supply Override – Recipients may receive a one-time maintenance supply override for a specific medication if appropriate medical justification is submitted. An example of acceptable medical justification would include a pharmacist's inability to contact a provider to change the quantity of a prescription. This is a one-time override only.
- Stable Therapy Override – Recipients may receive an override that allows a maintenance supply prescription to be filled when stable therapy requirements are not met in the Alabama Medicaid claims processing system. For example, the recipient meet's stable therapy requirements but has paid cash for previous prescriptions. Documentation of stable therapy via receipts, pharmacy printouts, etc. must be provided. Additionally, medications such as birth control pills packaged in three-month supply containers may be approved for an initial override of stable therapy requirements.

J. Short Acting Opioid Naïve Override

Effective November 1, 2018, Alabama Medicaid will implement limits on short acting opiates for opioid naïve recipients. The Agency defines "opioid naïve" as a recipient with no opioid in the past 180 days.

Edit Details:

- A 7-day supply limit for adults age 19 and older
- A 5-day supply limit for children age 18 and younger
- A maximum of 50 morphine milligram equivalents (MME) per day allowed on a claim for an opioid naïve recipient
- Any claim for a short acting opioid for an opioid naïve recipient exceeding the maximum days' supply limit or MME limit will be denied.
- Claims prescribed by oncologists will bypass the edit.
- Long term care and hospice recipients are excluded.
- Refills of remaining quantities and/or new prescriptions filled within 180 days of the initial opioid naive claim **will require an override.**
  - Refills of remaining quantities of prescriptions that are partially-filled will be allowed per State and federal law* but will require an override through Medicaid.
  - For adults, the refill of the quantity remaining on the partial fill **will not count** towards the prescription limit if filled within 30 days of the original prescription. Monthly maximum unit quantities still apply.
- A Recipient Information Sheet for prescribers and pharmacists to provide to recipients can be found at http://medicaid.alabama.gov/documents/9.0_Resources/9.4_Forms_Library/9.4.13_Pharmacy_Services/9.4.13_Opioid_Naive_Recipient_Handout.pdf.

IMPORTANT: A recipient may not pay cash for the remaining amount over 7 days for the same prescription of a Medicaid-paid opioid claim (ie a single fill/dispense/claim may not be 'split billed' to both Medicaid and cash). If the prescription to be paid by Medicaid exceeds the drug's limit allowed, an override may be requested. Only if the override is denied, then the excess quantity above the maximum unit limit is deemed a non-covered service, and the recipient can be charged as a cash recipient for that amount *in excess* of the limit. A prescriber must not write separate prescriptions, one to be paid by Medicaid and one to be paid as cash, to circumvent the override process. FAILURE TO ABIDE BY MEDICAID POLICY MAY RESULT IN RECOUPMENTS AND/OR ADMINISTRATIVE SANCTIONS. Source: Provider Billing Manual 27.2.3

Section Two
Override Form: Patient Information

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

Section Three
Override Form: 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
Override Form: Dispensing Pharmacy Information

- Information in this area may be completed by the pharmacy.
- Enter the pharmacy name and NPI number.
- Record the NDC number (or J Code if applicable) for the requested drug.
- Enter the quantity per month of the NDC being requested.
- Enter the phone number and fax number with area codes.

Section Five
Override Form: Drug/Clinical Information

- This section must be filled out for all requests.
- Check the appropriate box for the type of request being submitted.
- Record the name of the drug, the strength requested, and the date requested.
- If the request is for an **Early Refill or Accumulation Edit**, indicate the reason for the request by checking the appropriate box. Additional documentation justifying the request must accompany the form as indicated.
- If the request is for a **Maximum Unit, Maximum Cost, or Maintenance Supply** override, indicate the diagnosis and medical justification for the requested claim on the override form.
- For **Therapeutic Duplication, Ingredient Duplication,** or **Prescription Limit Switch Over** requests, the names of **both** drugs involved need to be included,

along with an appropriate diagnosis, stop date(s), NDC number(s) and reason for change.

- For **DAW=1** requests, check the appropriate box indicating if the override is an initial request or renewal request.
- For **Short Acting Opioid Naive** requests, indicate the diagnosis and include medical justification for why the patient needs more than 5-7 days of the prescribed medication. Additionally, all questions included under the drug information section of the override form must be completed for requests to be considered for approval.
- Any information provided as supportive medical justification must be available in the patient record for review upon request.

Attachment A
Outpatient Gene Therapy Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record
- The requested agent being prescribed must be in consultation with a specialist with expertise in the diagnosis of the condition
- Required monitoring and pre-treatment attestation must be submitted with request
- The requested agent must be administered in an outpatient setting
- For complete criteria for specific therapies, please contact the Alabama Medicaid Agency Clinical Services and Support Division at 334-242-5050.

Prior Treatment

- The patient must meet all FDA approved requirements or exclusions

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested

PA Approval Timeframes

- Approval may be given for up to 6 months or until patient exceeds FDA approved age range, whichever comes first.