Title
REDACTED DRUG NAME Drug Overview, SOP 95-005

Summary
This standard operating procedure (SOP) gives important information for the medication REDACTED DRUG NAME, including referral information, patient and copayment assistance programs, prior authorizations, appeals, bridge shipments, and emergency STAT orders.

Drug Information

The following information applies to this Standard Operating Procedure (SOP):

- REDACTED DRUG NAME (Carglumic Acid) is an oral drug, which has been approved by the Food and Drug Administration (FDA) on March 18, 2010 used for the treatment of hyperammonaemia in patients with N-acetylglutamate synthase deficiency (NAGS Deficiency).
- The initial daily dose ranges from 100 to 250mg/kg, adjusted thereafter to maintain normal plasma levels of ammonia.
- Recordati is the manufacturer.
- REDACTED Health Group (REDACTED) is the exclusive dispensing Specialty Pharmacy (SP).
- Emergency, **STAT** order, services are provided by REDACTED's Wholesale department 24 hours a day, 7 days a week to patients in a hospital setting that are ultimately transitioned to home care following their discharge from the hospital.

  Important: **STAT** orders are required to be delivered within 6 hours.

Referral Information

The following applies to referrals:

Referral Intake

- Follow the standard insurance verification procedures to create an REDACTED account and clear to pharmacy.
- When a new referral is received for REDACTED DRUG NAME, the data imagers send an email to the Pharmacy Case Manager (PCM) and the program manager.
- Direct referrals from the physician and/or hospital are accepted.
- If a referral is received for a baby or newborn, confirm if the patient is in the hospital and email the program manager to verify if a STAT order is needed.

Referral Process

- REDACTED DRUG NAME follows the standard clearance process.
- Confirm if the prescriber falls under Physician Concierge before working the account.

Note:

-
    - Refer to REDACTED to look up the provider and information on how to work concierge accounts.
    - Refer to REDACTED for additional information on clearance processes.
- The PAC representative MUST attempt to obtain prior authorization when required by the payer.

    Note: Refer to REDACTED for additional information on obtaining a prior authorization.

REDACTED DRUG NAME Patient Assistance Program

Note: For ALL insurance and financial concerns, Recordati is willing to review for further assistance if a signed HIPAA authorization is on file. Contact the program manager via email; they follow up with the REDACTED Account/Product Management to assist with outreach.

Refer to the information below for the REDACTED DRUG NAME Patient Assistance Program (PAP):

- When a patient does NOT have insurance, contact REDACTED program manager for PAP review.
- For assistance, patients MUST:
    - Provide proof of income.
    - Complete the **REDACTED DRUG NAME Patient Assistance Program (PAP) Application.**
    - Complete the **REDACTED DRUG NAME Attestation Form.**

COVER U

Field	Description
Claim Center	REDACTED
Status	A
Sequence	50
Address Sequence	1

Field	Description
Medical Benefit Carrier	FNL waiver
Effective Date	Today's date through years end
Instructions tab	**Line 1:** Information and reporting purposes ONLY. **Line 2:** - Date request was received - ALL plans provided to the patient **Line 3:** Indicate Status as Pending

- Update REDACTED with outcome of patient's decision regarding the alternate plans provided.
- If the patient has **NOT** been approved for alternate funding, they are approved for PAP until the end of the calendar year.

Alternative plan options, provided by REDACTED during the Cover U process, MUST be considered before the patient is considered for PAP.

Note: The estimated processing time frame is usually two to three business days.

- Cover U Requests are received via:
    - Email
    - Incoming call from patient/family members
- Confirm the type of plan to research:
    - Medicare Part D plan or Medicare Supplemental plans AKA (Medigap)
    - Medicare Advantage plans (Part C)
    - Commercial Health Insurance
      Refer to the: eHealth Website
    - Affordable Care Act plans
      Refer to the: Healthcare Marketplace Website
    - Managed Medicaid
    - Straight Medicaid
- Users **MUST** enter a **FAP** type chart note using the Cover U template in REDACTED.
- Information needed to complete research:
    - Date of birth
    - Gender
    - State and county of permanent residence
    - Drug name
    - Current plan type
    - Desired plan type
    - Qualifying event, if any (if open enrollment is closed)
    - Family size and household income.

- Make a list of located plans and plan contact information.
- Verify if the plan is contracted with REDACTED and the drug is covered using REDACTED.
- Once **ALL** required information is obtained, contact patient and provide the list of plans and their contact information.
- Once patient has been contacted and provided with plan information, enter the Cover U claim center using the information below:

Patient Assistance Program (PAP)

Refer to the table below to process PAP referrals:

Field	Description
Claim Center	REDACTED
Pricing ID (PID)	REDACTED
Therapy Code	REDACTED
Patient ID	REDACTED ID

- Users **MUST** update the following:
  - **Status Screen:** REDACTED
  - **Chart Note**: **FAP** type chart note; **Financial Assistance Request** template
- Patients approved for PAP are eligible for up to twelve monthly shipments per calendar year.

  Important: The program manager creates an On-Demand Task (ODT) for six months from the approval start date. A patient care advocate (PCA) follows up with the patient for insurance and/or income changes before receiving shipments for the remainder of their eligibility period.

- The patient MUST sign for each shipment.

Medicare Part D Beneficiaries

- A patient who expresses a financial hardship due to the cost of medication can be considered for PAP.
- Upon approval, a letter is sent to the patient and a phone call is made to the Part D plan notifying them the patient has been both approved for PAP and is provided medication outside their Part D benefit.

REDACTED DRUG NAME Copayment Assistance Program

The REDACTED DRUG NAME Copay Assistance Program is managed internally by REDACTED for patients experiencing financial hardship due to the cost of their REDACTED

DRUG NAME treatment. Contact the program manager to get the patient reviewed for and enrolled in copay assistance.

- Refer to the following commercial REDACTED DRUG NAME Copay Assistance Program guidelines:
    - Proactively offer to patients with copays of any amount.
    - Approved to a maximum of $15,000 per calendar year.
    - $15,000 of the approved copay assistance amount may be applied to a patient's deductible.

Note: The patient is responsible for amounts exceeding their approved copay assistance amount.

- Recordati may consider additional funding. Contact the program manager via email who alerts the account manager to initiate the request.
- NOT valid for prescriptions eligible for reimbursement by any federal or state healthcare program to include:
    - Champus (TRICARE)
    - Medicaid
    - Medicare
    - Medicare Advantage plans
    - PCIP
    - TRICARE
    - Veterans Administration
    - Any other state or federal program

        Important: Patients that need additional funding or have federal or state health care programs are to be referred to Healthwell Foundation at 800-675-8416 to apply for alternate financial assistance.

- An approval letter is mailed to each patient at the time of enrollment into the REDACTED DRUG NAME Copay Assistance Program.

- Refer to the table below to process referrals for patient assistance.

Field	Description
Claim Center	REDACTED
Pricing ID (PID)	REDACTED
Therapy Code	REDACTED
BIN	REDACTED
Patient ID	REDACTED
Group ID	REDACTED
PCN	CN

Bridge Shipments

The bridge shipment procedure applies to the distribution of REDACTED DRUG NAME in the United States for patients with confirmed NAGS deficiency. Patients are reviewed and approved for bridge by the program manager.

Note: For **ALL** insurance and financial concerns, Recordati is willing to review for further assistance if a signed HIPAA authorization is on file. Contact the program manager via email; they will follow up with the REDACTED Account/Product Management to assist with outreach.

- During a potential interruption, free product is provided to the patient through REDACTED.
- Bridge Shipment Inclusion Criteria: When a patient has been discharged from a hospital and the prescribed REDACTED DRUG NAME is **NOT** covered under the patient's insurance, REDACTED **MUST** verify if a patient qualifies for a bridge shipment which is based on meeting one of the following criteria below:
    - Newly diagnosed/confirmed with NAGS deficiency.
    - To be discharged/recently discharged from the hospital without having adequately addressed the reimbursement of REDACTED DRUG NAME.
    - Applied to REDACTED for CAP/PAP but has **NOT** received a final response.
    - Changed insurance and benefit investigation is incomplete at the time of the next shipment.

        Important: When the patient meets the inclusion criteria, REDACTED authorizes 2 weeks of the free drug as a bridge shipment with management approval.

- Clearance representative enters the patient qualifies for a bridge shipment in an **INTAK** type chart note.

- Clearance representative emails the chart note to the program manager to ask for approval for the bridge shipment.

  Note: The program manager enters an **INTAK** type chart note with an approval or denial.

- Refer to the table below to process bridge shipments:

Field	Description
Claim Center	REDACTED **Note: NO** personal pay.
Address Sequence	1
Pricing ID (PID)	REDACTED
Billing Sequence	Primary
Group Number	N/A
Effective Date	Date bridge was approved
Therapy Type	REDACTED
Patient ID number	REDACTED ID

Prior Authorization

When the payer determines a prior authorization is required, the PAC representative attempts to obtain the prior authorization using the steps provided in the REDACTED

Appeals Procedure/PA Denial

Refer to the following information when working appeals or PA denial.

Patient Representative

1. Obtain the appeal information from the plan.
2. Send an email notification of the PA denial to both the PCM and PM including any appeal requirements given from the plan. Send email to both distribution lists:
   - Rare Clinical META (RareClinicalMETAREDACTED)
   - REDACTED DRUG NAME Program Manager (REDACTED DRUG NAMEProgramManagREDACTED)

Case Manager (CM)

1. Receive request from representative via email distribution mailbox.

2. Notify the prescriber's office that a PA was denied and appeal packet will be sent via fax. Verify the fax number and include Example appeal letter NAGs or open in the appeal packet.
3. Send a fax to the prescriber's office.
4. Enter the chart note.
5. Call prescriber to give next steps and determine if pursuing appeal.
   - Notify the Program Manager if the prescriber is:
     - Going to pursue appeal. The Program Manager will start the bridge process.
     - NOT going to submit appeal. Program Manager will move patient to inactive.

Program Manager (PM)

1. Receive information from representative via email distribution mailbox.
2. Receive update from PCM with prescribers wishes.
3. Create Chart Note with details pertaining to request.
   - Prescriber is going to pursue appeal, start the bridge process.
   - Prescriber is NOT going to submit appeal, move patient to inactive.
4. Communicate to PAC representative with next steps for prescriber appeal decision.

Representative

1. Receive communication from the Program Manager with next steps for prescriber appeal.
   - Prescriber is NOT going to submit appeal for PA denial: Unenroll patient account for therapy.
   - Prescriber does pursue an appeal for the denied PA: See REDACTED

Representative Denied PA Appeal Follow Up

When Case Manager advises that the prescriber will appeal PA denial, complete the following steps.

1. Contact the plan every five business days to determine if the appeal has been submitted for a total of three attempts over 15 business days.

   Important: After each status check the PAC representative will notify the PM and PCM via email of the outcome.

   - The appeal has not been submitted:
     a. Enter an REDACTED type chart note using **PA Denied Outbound Call Template-Rare Disease.**
     b. Notify PM and CM appeal has **NOT** been submitted.

   c. Complete the clearance task using **Reason Code: PA Denied.**
- The appeal has been submitted: Follow up every 48 hours or within the follow up cadence provided by the plan until a decision has been made.

2. Receive notice of appeal status.
- Appeal is approved:
   a. Enter an REDACTED type Chart Note using the **Prior Authorization Approved-Rare Disease Template**
   b. Notify the PM and PCM of approval via email.
   c. Finalize benefit investigation.
   d. Complete clearance task using **Reason code: Insurance cleared.**
- Appeal is denied:
   a. Enter an **AUTH** type chart note using **PA Denied Outbound Call Template-Rare Disease.**
   b. Notify the PM and PCM of denial via email.
    RESULT: PCM will notify prescriber's office of PA denial to determine if another appeal will be submitted.
  - Another appeal will be submitted: See Appeals Procedure/PA Denial, Step 1.
  - Another appeal will **NOT** be submitted: Appeals Procedure/PA Denial, Step 12.

REDACTED DRUG NAME Emergency STAT Orders

Refer to the following information to handle REDACTED DRUG NAME Emergency Orders:

- When a call is received regarding REDACTED DRUG NAME, be sensitive to the caller's needs and listen for key words such as:
  o Hospitalized
  o Emergency
  o Urgent
  o Specialty Distribution
- Warm transfer call to the REDACTED Wholesale Team at 214500
- When the hospital wants a direct number to Wholesale, provide 877-900-9223
- NO referrals, including prescriptions are required, or can be accepted
  o Refer to: REDACTED
    Section: **Emergency Shipment Request for STAT REDACTED DRUG NAME Orders**
- REDACTED
- Once Wholesale completes their procedure, an email is sent to the **REDACTED DRUG NAME Emergency** distribution list in Outlook including the REDACTED DRUG NAME Emergency Outreach template with the Subject line: REDACTED DRUG NAME Stat Shipment to <hospital name/city/state>.
- The program manager notifies Recordati of any **STAT** orders via email.