



STATE BOARD OF PHARMACY

800 SW Jackson, Suite 1414
Topeka, Kansas 66612-1244
www.pharmacy.ks.gov (785)296-4056

STATEWIDE PROTOCOL:

**Group A Streptococcal
Pharyngitis – Under 18**

Protocol for Testing and Initiation of Therapy for
Suspected Acute Group A Streptococcal Pharyngitis in Patients Under 18 years

1. Authorization

This Protocol is issued pursuant to K.S.A. 65-16,131, which allows a pharmacist to initiate therapy for streptococcal pharyngitis pursuant to a statewide protocol adopted by the Kansas Collaborative Drug Therapy Management Advisory Committee. The intent of the Protocol is to provide testing and treatment for acute patients, not chronic carriers. A pharmacist shall engage in this Protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this Protocol to initiate CLIA-waived point-of-care testing for acute Group A streptococcal (GAS) pharyngitis and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute GAS pharyngitis infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol and their accompanying legal guardian.

A pharmacist shall ensure that a copy of the Pediatric Advanced Life Support (PALS) criteria for vital signs in children is available in the pharmacy for immediate reference (see Appendix B).

Terms identified in this Protocol shall have the meaning set forth in K.S.A. 65-1626, and amendments thereto. For purposes of this Protocol, “legal guardian” shall mean an individual who is either the natural parent of the minor child or a court-appointed guardian of the minor child responsible for the minor child’s health and welfare.

2. Evaluation Criteria

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat acute GAS pharyngitis infection shall treat patients according to current [IDSA guidelines](#).

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Inclusion criteria:

Any patient who presents to the pharmacy with a legal guardian and meets **all** the following criteria:

- Age 6 years or older with presence and written consent of a legal guardian;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula);
- Reported symptom onset < 96 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy with the legal guardian until antibiotics are dispensed.

Exclusion criteria:

Any individual who meets **any** of the following criteria:

- Under 6 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- Resident of a long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
 - Muffled voice;
 - Drooling;
 - Stridor;
 - Respiratory distress;
 - "Sniffing" or "tripod" positions;
 - Fever and rigors;
 - Severe unilateral sore throat;
 - Bulging of the pharyngeal wall/floor or soft palate;
 - Trismus;
 - Crepitus;
 - Stiff neck; or
 - History of penetrating trauma to oropharynx;
- History of tonsillectomy within the past 30 days;
- CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician's office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record;
- Patient is receiving hemodialysis;
- Clinical instability of a patient based on the clinical judgment of the pharmacist;
- Acute altered mental status of the patient (e.g., a change from baseline);
- Oxygen saturation (SpO₂) < 94% via pulse oximetry;
- Any two of the following: systolic blood pressure, diastolic blood pressure, pulse, or respiratory rate outside the PALS criteria based on the patient age, or temperature > 100.4 degrees Fahrenheit;
- Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit; or
- Temperature < 96.8 degrees Fahrenheit.

Absent or unobtainable vital signs should be considered abnormal vital signs for purposes of this Protocol.

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol and the patient's legal guardian on all the following:

- Appropriate patient care including symptom control, hygiene, and infection control measures;
- [CDC guidelines](#) and [KDHE guidelines](#) (see pg 53) that a patient with a confirmed diagnosis of acute GAS pharyngitis should stay home from work, school, or daycare until they are afebrile for at least 24 hours after starting antibiotic therapy;
- Referral for any unrelated symptoms or patient complaints not addressed under this Protocol;
- Medication counseling pursuant to K.A.R. 68-2-20; and
- Signs and symptoms that warrant emergency medical care.

3. Initiation of Therapy and Procedures

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's acute GAS pharyngitis status.

- If positive, the pharmacist may proceed to consideration for immediate antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient and legal guardian on the risk of a false-negative test result and on appropriate patient care (stay home for at least 24 hours after fever subsides, drink plenty of fluids, treat symptoms as needed, etc.) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions.

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)

- Allergic reactions to clindamycin
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

The pharmacist may initiate antibiotic therapy only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Antibiotic Therapy

The pharmacist is authorized to order and dispense one of the following medication regimens to a patient that meets the evaluation inclusion criteria unless an identified contraindication applies for the patient.

Selection of antibiotic regimen will follow the ordered preference listed below. A lower-ranked regimen will only be prescribed if the patient or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen, or if the drug is not commercially available or appears on the [FDA drug shortages list](#). The pharmacist may select the dosage form (i.e., liquid or chewable tablet) of any treatment based on the need or preference of the patient or legal guardian. If the patient is currently receiving another antibiotic, the pharmacist may utilize a lower-ranked regimen. However, a change to the dosage of the patient's current medication or the treatment selected by the pharmacist to treat the acute GAS pharyngitis shall not be considered. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction.

If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

A. First-line treatment

a. Amoxicillin

- i. Contraindication: Penicillin allergy
- ii. Dosing: 25 mg/kg (max 500 mg) PO twice daily x 10 days, or

b. Penicillin

- i. Contraindication: Penicillin allergy
- ii. Dosing
 1. Penicillin V, oral
 - a. ≤27 kg: 250 mg PO twice daily x 10 days, or
 - b. >27 kg: 500 mg PO twice daily for 10 days
 2. Penicillin G benzathine, to be administered by the Pharmacist
 - a. ≤27 kg: 600,000 units IM, single dose, or
 - b. >27 kg: 1.2 million units IM as a single dose

B. Second-line treatment

a. Cephalexin

- i. Contraindications
 1. Cephalosporin allergy
 2. Severe penicillin allergy
- ii. Dosing: 20 mg/kg (max 500 mg) PO twice daily x 10 days

b. Cefadroxil

- i. Contraindications
 1. Cephalosporin allergy

2. Severe penicillin allergy
 - ii. Dosing: 30 mg/kg (max 1g) PO daily x 10 days
- C. Third-line treatment
 - a. Azithromycin
 - i. Contraindication: Macrolide allergy
 - ii. Dosing: 12 mg/kg (max 500 mg) PO once daily x 5 days
 - b. Clindamycin
 - i. Contraindication: Clindamycin allergy
 - ii. Dosing: 7 mg/kg (max 300 mg) PO three times daily x 10 days
- D. Fourth-line treatment
 - a. Clarithromycin
 - i. Contraindication: Macrolide allergy
 - ii. Dosing: 7.5 mg/kg/dose (max 250 mg/dose) PO twice daily x 10 days
- E. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
 - a. Acetaminophen PO according to OTC dosing recommendations; and
 - b. Ibuprofen PO according to OTC dosing recommendations.

In any case where amoxicillin is not the selected regimen, the pharmacist shall document the rationale for selecting the antibiotic dispensed. Documentation may include medication sensitivity, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up with patient's legal guardian within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the legal guardian follows-up with the pharmacist after receiving therapy and within the therapy regimen period, the pharmacist may utilize their professional judgment to dispense replacement therapy due to unanticipated loss or adulteration of the previous prescription dispensed. The pharmacist shall not substitute alternate therapy.
- Refer to a primary care provider or urgent/emergent treatment facility if any of the following are reported:
 - Significant deterioration in condition or new evidence of clinical instability;
 - Onset of symptoms inconsistent with acute GAS pharyngitis infection or indicative of serious complications; or
 - Medication adverse effects severe enough to warrant discontinuation.

4. Documentation and Recordkeeping

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for acute GAS pharyngitis pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Elements required by K.S.A. 65-1642 and K.A.R.68-7-14;
- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;



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- Patient and legal guardian informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 10 years from the date of assessment, testing, and/or dispensing, or until the patient turns 20 years old, whichever is longer. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

5. Training and Counseling

Prior to initiating testing and dispensing antibiotic therapies under this protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy from a provider accredited by the Accreditation Council for Pharmacy Education (ACPE). Additionally, the pharmacist shall maintain knowledge of the Infectious Disease Society of America (IDSA)'s current recommendations for the treatment of acute GAS pharyngitis. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

6. Notification

The pharmacist shall ask the legal guardian of the patient tested under this Protocol for the name and contact information of a primary care provider. If a primary care provider is identified, the pharmacist shall provide a summary of the patient encounter to the provider within seven days, including at least the patient's name, date of birth, acute GAS pharyngitis test results, any medication dispensed, and follow-up plan.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient and legal guardian with a copy of the test result.



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7. Signed Protocol

Each pharmacist utilizing this Protocol shall maintain a copy of the signed and dated Protocol for ten years from the date of last assessment, testing, or dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has provided services.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number
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SIGNATURE

DATE SIGNED

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Acute GAS Pharyngitis – Under 18
Appendix A**

**Pharmacist Assessment, Evaluation and Prescribing Protocol Form:
Acute Group A Streptococcal Pharyngitis, Under 18**

PATIENT INFORMATION

Name		Date of Birth	Age	
Legal Guardian Name		Phone	Email	
Address				
City	State	Zip	County	
Primary Care Provider				
Medication Allergies				
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):				
Treatments tried for current condition (if none, indicate N/A):				

PATIENT ELIGIBILITY (Legal Guardian may respond on behalf of Patient)

<input type="checkbox"/> Yes <input type="checkbox"/> No Are you 6 years of age or older?
<input type="checkbox"/> Yes <input type="checkbox"/> No Are you pregnant or breastfeeding?
<input type="checkbox"/> Yes <input type="checkbox"/> No Are you experiencing any altered mental status or change from normal cognition? If yes, explain:
<input type="checkbox"/> Yes <input type="checkbox"/> No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
<input type="checkbox"/> Yes <input type="checkbox"/> No Do you have a history of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis?
<input type="checkbox"/> Yes <input type="checkbox"/> No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxicillin, cephalexin, clarithromycin, or clindamycin?
<input type="checkbox"/> Yes <input type="checkbox"/> No Are you a resident of a nursing home or long-term care facility, in hospice, or receiving home health services?
<input type="checkbox"/> Yes <input type="checkbox"/> No Do you have a pending test for your symptoms (COVID, strep, flu)?
<input type="checkbox"/> Yes <input type="checkbox"/> No Have you had a tonsillectomy in the previous 30 days?
<input type="checkbox"/> Yes <input type="checkbox"/> No Are you receiving hemodialysis?
<input type="checkbox"/> Yes <input type="checkbox"/> No Do you have a history of chronic kidney disease or reduced kidney function?
When did your symptoms start? <input type="checkbox"/> More than four days ago. <input type="checkbox"/> Fewer than four days ago
Do you have any of the following symptoms (check all that apply)? <input type="checkbox"/> Fever <input type="checkbox"/> Sore throat <input type="checkbox"/> Pain swallowing <input type="checkbox"/> Swollen/tender cervical lymph nodes <input type="checkbox"/> Inflamed or swollen tonsils or uvula <input type="checkbox"/> Other:



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– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (please record values)	Refer to PCP if determined clinically unstable in pharmacist professional judgment or any of the following criteria:
Blood Pressure	Systolic blood pressure or diastolic blood pressure outside PALS criteria based on patient age (dual criteria)
Respiratory Rate	Respiratory rate outside PALS criteria based on patient age (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO ₂) < 94% via pulse oximetry
Pulse	Pulse outside PALS criteria based on patient age (dual criteria)
Creatinine Clearance	CrCl < 10 ml/min or unable to obtain
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
<input type="checkbox"/> Yes <input type="checkbox"/> No Acute altered mental status	Yes
Severe Symptoms of Respiratory Distress	Muffled voice; Drooling; Stridor; Respiratory distress; "Sniffing" or "tripod" positions; Fever and rigors; Severe unilateral sore throat; Bulging of the pharyngeal wall/floor or soft palate; Trismus; Crepitus; Stiff neck; or History of penetrating trauma to oropharynx.
Overt Viral Features	Conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 6 years or older with presence and written consent of a legal guardian;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula);
- Reported symptom onset < 96 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy with the legal guardian until antibiotics are dispensed.

Refer to PCP and exclude from testing if:

- Under 6 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;



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- Resident of a long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient’s reported symptoms;
- Severe symptoms of respiratory distress, including:
 - Muffled voice;
 - Drooling;
 - Stridor;
 - Respiratory distress;
 - "Sniffing" or "tripod" positions;
 - Fever and rigors;
 - Severe unilateral sore throat;
 - Bulging of the pharyngeal wall/floor or soft palate;
 - Trismus;
 - Crepitus;
 - Stiff neck; or
 - History of penetrating trauma to oropharynx;
- History of tonsillectomy within the past 30 days;
- CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician’s office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record;
- Patient is receiving hemodialysis;
- Clinical instability of a patient based on the clinical judgment of the pharmacist;
- Acute altered mental status of the patient (e.g., a change from baseline);
- Oxygen saturation (SpO2) < 94% via pulse oximetry;
- Any two of the following: systolic blood pressure, diastolic blood pressure, pulse, or respiratory rate outside the PALS criteria based on the patient age, or temperature > 100.4 degrees Fahrenheit;
- Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympenic) Fahrenheit; or
- Temperature < 96.8 degrees Fahrenheit.

CLIA-WAIVED POC TEST RESULT

- Positive for acute GAS pharyngitis (continue)
- Negative for acute GAS pharyngitis (refer to PCP + symptomatic treatment)

PATIENT ACTION

- Yes No Acute GAS pharyngitis Diagnosed
- Yes No Antibiotic Treatment Prescribed
- Yes No Refer to PCP



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 Appendix A

Therapy Options		
Acute GAS Pharyngitis Treatment		
Documentation of Rationale for Treatment Selection (if required):		
<input type="checkbox"/> Oral Amoxicillin	Dispense: <input type="checkbox"/> 500mg #20 <input type="checkbox"/> ____ mg #20 <input type="checkbox"/> alt dosage form: _____ No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days Sig Alt: _____
<input type="checkbox"/> Oral Penicillin V	Dispense: <input type="checkbox"/> 250mg #20 <input type="checkbox"/> 500mg #20 No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days; or Take one (500mg) by mouth twice daily for 10 days
<input type="checkbox"/> IM Penicillin G benzathine	Dispense: <input type="checkbox"/> 600,000 units IM, single dose <input type="checkbox"/> 1.2million units IM, single dose No refills	To be administered by the pharmacist
<input type="checkbox"/> Oral Cephalexin	Dispense: <input type="checkbox"/> 500mg #20 <input type="checkbox"/> ____ mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days Sig Alt: _____
<input type="checkbox"/> Oral Cefadroxil	Dispense: <input type="checkbox"/> 1g #10 No refills	Sig: Take 1 (one) (1g) by mouth daily for 10 days
<input type="checkbox"/> Oral Azithromycin	Dispense: <input type="checkbox"/> 500mg #5 <input type="checkbox"/> ____ mg #5 No refills	Sig: Take 1 (one) (500mg) by mouth daily for 5 days Sig Alt: _____
<input type="checkbox"/> Oral Clindamycin	Dispense: <input type="checkbox"/> 300mg #30 <input type="checkbox"/> ____ mg #30 <input type="checkbox"/> alt dosage form: _____ No refills	Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days Sig Alt: _____
<input type="checkbox"/> Oral Clarithromycin	Dispense: <input type="checkbox"/> 250mg #20 <input type="checkbox"/> ____ mg #20 <input type="checkbox"/> alt dosage form: _____ No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days Sig Alt: _____

PHARMACIST PRESCRIBER CERTIFICATION

Printed Name	License Number
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SIGNATURE

DATE



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PATIENT FOLLOW-UP

Assessment	Refer to PCP (if symptoms persist) <input type="checkbox"/> Yes <input type="checkbox"/> No
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PHARMACIST FOLLOW-UP CERTIFICATION

Printed Name	License Number
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SIGNATURE

DATE