

**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 - Adult**

Protocol for Testing and Initiation of Therapy for Suspected Acute Group A Streptococcal Pharyngitis in Adult Patients

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.

Terms identified in this Protocol shall have the meaning set forth in K.S.A. 65-1626, and amendments thereto.

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 and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- 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 until antibiotics are dispensed.

Exclusion criteria:

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

- Under 18 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 nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- 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; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
 - Two or more of the following criteria:
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >90 beats/min;
 - Respiratory rate >20 breaths/min;
 - Temperature < 96.8 degrees Fahrenheit; or
 - Temperature > 100.4 degrees Fahrenheit; or
 - Any one of the following criteria:
 - Acute altered mental status;
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >125 beats/min;
 - Respiratory rate >30 breaths/min;
 - Oxygen saturation (SpO₂) < 90% via pulse oximetry; or
 - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

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 on all the following:

- Appropriate self-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 or school until they are afebrile for at least 24 hours after starting antibiotic therapy;
- 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 or caregiver on the risk of a false-negative test result and on appropriate self-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](#). 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: 500 mg PO twice daily x 10 days, or
 - b. Penicillin
 - i. Contraindication: Penicillin allergy
 - ii. Dosing
 - 1. Penicillin V, oral – 500mg PO twice daily x 10 days
 - 2. Penicillin G benzathine – 1.2million units IM, single dose, to be administered by the pharmacist
- B. Second-line treatment
 - a. Cephalexin
 - i. Contraindications
 - 1. Cephalosporin allergy
 - 2. Severe penicillin allergy
 - ii. Dosing: 500 mg PO twice daily x 10 days
 - b. Cefadroxil
 - i. Contraindications
 - 1. Cephalosporin allergy
 - 2. Severe penicillin allergy
 - ii. Dosing: 1g PO daily x 10 days
- C. Third-line treatment
 - a. Azithromycin
 - i. Contraindication: Macrolide allergy
 - ii. Dosing: 500 mg PO once daily x 5 days
 - b. Clindamycin
 - i. Contraindication: Clindamycin allergy
 - ii. Dosing: 300 mg PO three times daily x 10 days

- D. Fourth-line treatment
 - a. Clarithromycin
 - i. Contraindication: Macrolide allergy
 - ii. Dosing: 250 mg 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 within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- 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;
- Patient 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.



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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. 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 guidelines 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 patient tested under this Protocol for the name and contact information of a primary care provider. If the patient identifies a primary care provider, 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 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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**STATEWIDE PROTOCOL:
Acute GAS Pharyngitis - Adult
Appendix A**

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

PATIENT INFORMATION

Name		Date of Birth	Age	
		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

<input type="checkbox"/> Yes <input type="checkbox"/> No Are you 18 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 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, cephalixin, 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?
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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**STATEWIDE PROTOCOL:
 Acute GAS Pharyngitis - Adult
 Appendix A**

- 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 < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO ₂) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
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 18 years or older and able to give informed consent;
- 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 until antibiotics are dispensed.

Refer to PCP and exclude from testing if:

- Under 18 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;
- Residents of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;



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Appendix A**

- 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; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
 - Two or more of the following criteria:
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >90 beats/min;
 - Respiratory rate >20 breaths/min;
 - Temperature < 96.8 degrees Fahrenheit; or
 - Temperature > 100.4 degrees Fahrenheit; or
 - Any one of the following criteria:
 - Acute altered mental status;
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >125 beats/min;
 - Respiratory rate >30 breaths/min;
 - Oxygen saturation (SpO₂) < 90% via pulse oximetry; or
 - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympenic) 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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**STATEWIDE PROTOCOL:
Acute GAS Pharyngitis - Adult
Appendix A****Therapy Options****Acute GAS Pharyngitis Adult Treatment**

Documentation of Rationale for Treatment Selection (if required):

<input type="checkbox"/> Oral Amoxicillin	Dispense: <input type="checkbox"/> 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days; or
<input type="checkbox"/> Oral Penicillin V	Dispense: <input type="checkbox"/> 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
<input type="checkbox"/> IM Penicillin G benzathine	Dispense: <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 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
<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 No refills	Sig: Take 1 (one) (500mg) by mouth daily for 5 days
<input type="checkbox"/> Oral Clindamycin	Dispense: <input type="checkbox"/> 300mg #30 No refills	Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days
<input type="checkbox"/> Oral Clarithromycin	Dispense: <input type="checkbox"/> 250mg #20 No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days

PHARMACIST PRESCRIBER CERTIFICATION

Printed Name	License Number
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SIGNATURE

DATE



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**STATEWIDE PROTOCOL:
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Appendix A**

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