

**ACUTE GROUP A STREPTOCOCCAL (GAS) PHARYNGITIS INFECTION
PROTOCOL FOR USE DURING THE COVID-19 (SARS-CoV-2) PANDEMIC v4
Approved 07/27/2021**

***UPDATE* to Protocol Requirements During the COVID-19 (SARS-CoV-2) Pandemic**

Due to the similarities in clinical presentation of GAS and COVID-19, persons with GAS symptoms must also be tested for SARS-Cov-2. Accordingly, pharmacists using this protocol to test for GAS and initiate the dispensing of antibiotic therapy must be able to test for SARS-CoV-2. Pharmacists unable to conduct a rapid SARS-CoV-2 test, or collect a sample for send-off testing, are not authorized to use this or any previously approved versions of the acute GAS protocols unless US Department of Health and Human Services or US Centers for Disease Control and Prevention release guidelines that allow for acute GAS testing in the absence of SARS-CoV-2 testing during the COVID-19 Pandemic.

To provide point-of-care COVID-19 testing pharmacists must:

- 1) Meet the requirements established by the Kentucky Board of Pharmacy and in accordance with the Governor's Executive Order to Prevent the spread of COVID19 in the Commonwealth.
- 2) Follow all criteria and procedures for point-of-care COVID-19 testing as outlined in the current [Kentucky Statewide Physician Protocol for Point of Care COVID-19 Testing](#) (except for reimbursement, unless applicable).
- 3) Comply with all current reporting requirements per the Kentucky Department of Public Health.

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotics to treat acute Group A streptococcal (GAS) pharyngitis infection. The purpose of this protocol is to ensure appropriate and timely antibiotic therapy for individuals with streptococcal pharyngitis following diagnostic confirmation via CLIA-waived point-of-care testing.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotics under this protocol, pharmacist(s) must have received 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, or by a comparable provider approved by the Kentucky Board of Pharmacy. Additionally, pharmacist(s) must maintain knowledge of the Infectious Disease Society of America (IDSA)'s current guidelines for the treatment of GAS pharyngitis.¹

Provider of Training: _____

Date Training Completed: _____

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute GAS infection will treat individuals according to current IDSA guidelines.¹

Inclusion criteria:

Any individual who presents to the pharmacy and meets **ALL** of the following inclusion criteria:

- Age 5 years or older (with consent of a parent/guardian if < 18 years old)
- Complaint of any sign or symptom consistent with GAS pharyngitis (sore throat, pain on swallowing, fever, headache, swollen or tender cervical lymph nodes, inflamed or swollen tonsils or uvula)
- Positive GAS result via CLIA-waived point-of-care test

Exclusion criteria:

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

- Age < 5 years old
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS- induced glomerulonephritis
- Other antibiotic therapy prescribed for sore throat or upper respiratory infection within the previous 30 days
- Clinically unstable based on the clinical judgment of the pharmacist or any 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
 - Temperature >103 °F (taken orally)
- Presenting with overt viral features, such as: rhinorrhea, cough, oral ulcers, and/or hoarseness

Individuals who do not qualify for CLIA-waived testing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Individuals who do not qualify for antibiotic dispensing following testing will be referred for additional evaluation when the pharmacist has high suspicion of a false- negative result, determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

¹ *Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America.* Available online at http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_By_Organ_System-81567/Lower/Upper_Respiratory/Streptococcal_Pharyngitis/

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of one of the following medication regimens to an individual meeting criteria:

First-line Treatment (unless contraindicated due to history of penicillin allergy)

- 1. Amoxicillin PO 25mg/kg (max = 500 mg) twice daily for 10 days or 50 mg/kg (max 1000 mg) once daily for 10 days**

Second-line Treatment (for those with mild allergic reactions e.g. rash to penicillin)

- 2. Cephalexin PO 20 mg/kg/dose (max 500 mg/dose) twice daily for 10 days**

Third-line Treatments (for those with mild allergies to penicillin and cephalosporins or severe reactions e.g. anaphylaxis to penicillin)

- 3a. Azithromycin PO 12 mg/kg (max 500 mg) once daily for 5 days**
- 3b. Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days**
- 3c. Clarithromycin PO 7.5 mg/kg/dose (max 250 mg/dose) twice daily for 10 days**

Adjunctive therapy may be useful for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis and should be considered as an adjunct to an appropriate antibiotics.

Acetaminophen PO; follow OTC dosing recommendations

Ibuprofen PO; follow OTC dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform CLIA-waived point-of-care test to determine between acute GAS and viral pharyngitis

- If positive, continue to evaluate with protocol
- If negative,
- Adult: no back up throat culture needed for adults
- Children and adolescents (<18 y/o): back up throat culture must be done, thus referral to primary care provider or urgent treatment center is required

Antibiotic therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Assess for Relevant Medical and Social History

- Patient demographics and weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current Medications
- Medication allergies and hypersensitivities

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

Selection of antibiotic regimen will follow the ordered preference listed above. A lower-ranked regimen will only be prescribed if the individual or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen. The pharmacist will assess reported drug allergies for validity by reviewing the individual's pharmacy record and documenting the reported reaction. In any case where amoxicillin is not the selected regimen, the pharmacist will document the clinical reasoning for the selection.

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per IDSA guidelines people with acute GAS pharyngitis should stay home from work, school, or daycare until they are afebrile and until 24 hours after starting appropriate antibiotic therapy

Individuals receiving antibiotics under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document via prescription record each person who is tested for GAS under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of the manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used to determine GAS status

- Documentation that the individual (or caregiver) received the education required by this protocol
- Documentation of clinical follow up as appropriate

NOTIFICATION

Pharmacist(s) shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual’s name, date of birth, GAS test results, medication dispensed, and follow-up plan, within 2 business days.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving medications under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than 60 days.

SIGNATURES

Prescriber Name

Date

Prescriber Signature

Pharmacist Name

Date

Pharmacist Signature