Pharmacy Name: _____

Pharmacy Permit Number: _____

ACUTE GROUP A STREPTOCOCCAL (GAS) PHARYNGITIS INFECTION PROTOCOL v5
Approved 01/24/2024

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]

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute GAS infection will treat individuals according to current IDSA guidelines or in accordance with the Center for Disease Control and Prevention.[1,2]

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

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[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/

[2] https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html

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
- Presenting with overt viral features, such as: rhinorrhea, cough, oral ulcers, and/or hoarseness
- Presenting with a stiff neck consistent with meningismus

All individuals who do not qualify for antibiotic dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate.

MEDICATIONS

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

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

1a. Amoxicillin PO 25 mg/kg/dose (max 500 mg/dose) twice daily for 10 days

1b. Amoxicillin PO 50 mg/kg/dose (max 1000 mg/dose) once daily for 10 days

Second-line Treatments (for those with mild allergic reactions e.g. rash to penicillin or first-line treatment appears on the FDA Shortage List)

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

2b. Cefadroxil PO 30 mg/kg/dose (max 1000 mg/dose) once daily for 10 days

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

3a. Azithromycin PO 12 mg/kg/dose (max 500 mg/dose) day 1 , then 6 mg/kg/dose (max 250 mg/dose) once daily for days 2 through 5

3b. Azithromycin PO 12 mg/kg/dose (max 500 mg/dose) once daily for 5 days

3c. Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days

3d. 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 antibiotic.

- **Acetaminophen** PO; follow over the counter (OTC) dosing recommendations

- **Ibuprofen** PO; follow over the counter (OTC) dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform CLIA-waived point-of-care test to distinguish 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

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
- Upon request, documentation for work/school absence

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 2:171 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of parental consent for individuals under age 18
- 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 receiving treatment 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 authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Kentucky License Number

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.