PRIOR AUTHORIZATION POLICY

POLICY: Antibiotics – Synercid Prior Authorization Policy
- Synercid® (quinupristin and dalfopristin intravenous infusion – Pfizer)

REVIEW DATE: 07/12/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Synercid is indicated in adults for the treatment of **complicated skin and skin structure infections** caused by *Staphylococcus aureus* (methicillin-susceptible) or *Streptococcus pyogenes*.[1] To reduce the development of drug-resistant bacteria and maintain effectiveness of Synercid, it should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Guidelines

According to the Infectious Diseases Society of America (IDSA) guidelines for the diagnosis and management of skin and soft tissue infections (SSTIs) [2014], oral antibiotics such as penicillin VK, cephalosporin, dicloxacillin, and clindamycin can be used for mild nonpurulent SSTI (i.e., necrotizing infection, cellulitis, erysipelas).[2] For moderate nonpurulent SSTI, intravenous (IV) antibiotics such as penicillin, ceftriaxone, cefazolin, and clindamycin are recommended. For moderate purulent SSTIs, empiric treatment can be started with trimethoprim/sulfamethoxazole (TMP/SMX) or doxycycline. For methicillin-resistant *Staphylococcus aureus* (MRSA) infections, TMP/SMX is the recommended therapy. Cephalexin or dicloxacillin are usually effective for methicillin-susceptible *Staphylococcus aureus* (MSSA) infections. For severe purulent SSTI, empiric therapy with vancomycin (IV), daptomycin, linezolid, Vibativ® (telavancin intravenous infusion), or Teflaro® (ceftaroline

intravenous infusion) are recommended. All of these agents are active against MRSA strains. For severe purulent SSTI caused by MSSA, therapy can be switched to nafcillin, cefazolin, or clindamycin. Synercid is recommended as an alternative in patients with severe penicillin hypersensitivity for the treatment of necrotizing infections of the skin, fascia, and muscle.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Synercid. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

- **Synercid® (quinupristin and dalfopristin intravenous infusion – Pfizer) is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

1. **Skin and Skin Structure Infections, Complicated.** Approve for 1 month if the patient meets the following (A and B):
   A) Patient has an infection that is proven or strongly suspected to be caused by *Staphylococcus aureus* (methicillin-susceptible) or *Streptococcus pyogenes*; AND
   B) Patient has severe penicillin hypersensitivity.

Other Uses with Supportive Evidence

2. **Treatment of an Infection Caused by a Susceptible Microorganism**. Approve for 1 month if the patient meets the following (A and B):
   A) The microorganism is resistant to two other antibiotics; AND
   B) The microorganism is sensitive to Synercid.

3. **Continuation of Synercid Therapy.** Approve for 1 month if the patient meets the following (A and B):
   A) Patient was started on Synercid; AND
   B) Patient is continuing a course of therapy.

CONDITIONS NOT COVERED

- **Synercid® (quinupristin and dalfopristin intravenous infusion – Pfizer) is(are) considered experimental, investigational or unproven for ANY other use(s).**

REFERENCES

1. Synercid® for injection [prescribing information]. New York, NY: Pfizer; July 2018.
2. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2014;59:e10-e52.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/29/2022
Annual Revision	No criteria changes.	07/12/2023