PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Hereditary Angioedema – Icatibant Preferred Specialty Management Policy
- Firazyr® (icatibant subcutaneous injection – Takeda, generic)
- Sajazir™ (icatibant subcutaneous injection – Cycle)

REVIEW DATE: 09/27/2023

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

Icatibant is a synthetic decapeptide that is indicated for the **treatment of acute hereditary angioedema (HAE) attacks** in adults ≥ 18 years of age.[1,2]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of a Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of the Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Hereditary Angioedema – Icatibant Prior Authorization Policy* criteria but has not tried the Preferred Product, approval for the Preferred Products will be authorized. All approvals are for 1 year in duration, unless otherwise noted below.

Documentation: Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Preferred Product: generic icatibant, Sajazir
Non-Preferred Product: Firazyr

Hereditary Angioedema – Icatibant non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Firazyr	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Hereditary Angioedema – Icatibant Prior Authorization Policy* criteria; AND **B)** Patient has tried one of generic icatibant or Sajazir **[documentation required]**; AND **C)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient has met the standard *Hereditary Angioedema – Icatibant Prior Authorization Policy* criteria (1A) but has not met exception criteria (1B) and/or (1C): approve generic icatibant and Sajazir.

REFERENCES

1. Firazyr® [prescribing information]. Lexington, MA: Takeda; October 2021.
2. Sajazir™ subcutaneous injection [prescribing information]. Cambridge, UK: Cycle; June 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/21/2022
Annual Revision	No criteria changes	09/27/2023