DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Hereditary Angioedema – Icatibant Drug Quantity Management Policy – Per Days
- Firazyr® (icatibant subcutaneous injection – Takeda, generic)
- Sajazir™ (icatibant subcutaneous injection – Cycle)

REVIEW DATE: 02/08/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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, a synthetic decapeptide, is indicated for the treatment of **acute hereditary angioedema (HAE) attacks** in adults ≥ 18 years of age.[1,2]

Dosing
The recommended dose of icatibant is 30 mg administered by subcutaneous (SC) injection in the abdominal area.[1,2] Additional doses may be administered at intervals of at least 6 hours if response is inadequate or if symptoms recur. No more than three doses may be administered in any 24 hour period.

Availability
Icatibant is supplied in a single-use, prefilled syringe for SC injection which delivers 3 mL of a solution of icatibant 30 mg.[1,2] Cartons contain one single-use, prefilled syringe.

Guidelines

US HAE Medical Advisory Board guidelines (2020) recommend that all patients with laboratory confirmed HAE should have access to at least two standard doses of an approved on-demand medication for treatment of acute attacks.[3] On-demand treatment of attacks is most effective when administered early after attack onset.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of icatibant. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Firazyr® (icatibant SC injection, generic)	30 mg/3 mL prefilled syringes	12 syringes*	36 syringes*
Sajazir™ (icatibant SC injection)	30 mg/3 mL prefilled syringes	12 syringes*	36 syringes*

SC – Subcutaneous; * This is a quantity sufficient to treat at least four acute hereditary angioedema attacks in each 28-day period (retail) or 12 attacks in an 84-day period (home delivery), assuming that the patient requires three doses in a 24-hour period to treat each attack. If a patient requires additional icatibant doses for a subsequent attack, exceptions are provided based on the criteria below.

Hereditary Angioedema – Icatibant Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient requires additional doses of icatibant to treat a subsequent attack of hereditary angioedema (HAE), approve a one-time override for the requested quantity, not to exceed 3 additional prefilled syringes at retail or home delivery. Note: This exception applies to a patient who has already filled a supply of icatibant and requires additional medication for a subsequent attack before the next scheduled fill.

REFERENCES

1. Firazyr® subcutaneous injection [prescribing information]. Lexington, MA: Takeda; October 2021.
2. Sajazir™ subcutaneous injection [prescribing information]. Cambridge, UK: Cycle; September 2023.
3. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 guidelines for the management of hereditary angioedema. *J Allergy Clin Immunol Pract*. 2021;9(1):132-150.e3.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/18/2023
Annual Revision	No criteria changes.	02/08/2024