Medical Policy Bulletin

Title:
Dofetilide (Tikosyn®) Use in the Inpatient Setting
Policy #:
MA08.021c

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

An inpatient admission for the initiation, dose escalation or reinitiation of dofetilide (Tikosyn) is considered medically necessary and, therefore, covered for either of the following indications:

- For conversion of atrial fibrillation (AF) and atrial flutter (AFL) (AF/AFL) to normal sinus rhythm (NSR)
- For the maintenance of NSR (delay in time recurrence of AF/AFL) in individuals with AF/AFL of greater than 1 week's duration who have been converted to NSR

Dofetilide (Tikosyn) should be reserved for individuals in whom AF/AFL is highly symptomatic because the drug can cause life-threatening ventricular arrhythmias.

Therapy with dofetilide (Tikosyn) for initiation, dose escalation, and, if necessary, reinitiation, must be done according to the product labeling, for a minimum of 3 days in an inpatient setting that provides continuous electrocardiographic (ECG) monitoring in the presence of personnel trained in the management of serious ventricular arrhythmias. Additionally, individuals should not be discharged within 12 hours of electrical or pharmacologic conversion to NSR.

- For information on maintenance therapy with dofetilide (Tikosyn), refer to the Guidelines section of this policy.

NOT MEDICALLY NECESSARY

Dofetilide (Tikosyn) has not been shown to be effective in individuals with paroxysmal atrial fibrillation; therefore, it is considered not medically necessary and is not covered for this condition.

EXPERIMENTAL/INVESTIGATIONAL

All other uses of dofetilide (Tikosyn) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

There is no Medicare coverage determination addressing dofetilide (Tikosyn) in the inpatient setting; therefore, the Company policy is applicable.

BLACK BOX WARNINGS

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.

Dofetilide (Tikosyn) has arrhythmogenic potential and may cause serious ventricular arrhythmias, principally polymorphic ventricular tachycardia associated with QT-interval prolongation (i.e., Torsades de pointes). Because an increased QT interval and the risk of ventricular arrhythmias are directly related to plasma dofetilide (Tikosyn) concentrations, electrocardiographic (ECG) monitoring for excessive increases in the QT interval, dosage adjustment based on calculated creatinine clearance, and the avoidance of certain medications with known drug interactions are essential.

According to the manufacturer, initiation of therapy with dofetilide (Tikosyn) and any subsequent increase in dosage should be performed in a hospital setting where cardiac resuscitation can be performed and where the individual can be monitored by personnel trained in the management of serious ventricular arrhythmias. Continuous ECG monitoring should be performed for a minimum of 3 days (until steady-state plasma concentrations are obtained), or for a minimum of 12 hours after electrical or pharmacologic conversion to normal sinus rhythm, whichever is greater. A previously successful increase in the dosage of dofetilide (Tikosyn) does not eliminate the need for rehospitalization for a subsequent dosage increase.

BENEFIT APPLICATION

Subject to the applicable Evidence of Coverage, an inpatient admission for the initiation or reinitiation of dofetilide (Tikosyn) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

However, drugs that are identified in this policy as not medically necessary are not eligible for coverage or reimbursement by the Company.

Certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when dofetilide (Tikosyn) is covered under a member's medical benefit (Part B benefit). It does not address instances when dofetilide (Tikosyn) is covered under a member’s pharmacy benefit (Part D benefit).

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

The FDA approved the use of dofetilide (Tikosyn) for the labeled indications in October 1999.

PEDIATRIC USE
The safety and effectiveness of dofetilide (Tikosyn) in pediatric individuals have not been established.

Description

Dofetilide (Tikosyn) is an oral antiarrhythmic drug with Class III properties, which can cause cardiac action potential prolongation. The mechanism of action is the blockade of the cardiac ion channel that carries the rapid component of the delayed rectifier potassium current, IKr. At concentrations covering several orders of magnitude, dofetilide (Tikosyn) blocks only IKr, with no relevant block of the other repolarizing potassium currents (e.g., IKs, IK1). At clinically relevant concentrations, dofetilide (Tikosyn) has no effect on sodium channels (associated with Class I effect), adrenergic alpha-receptors, or adrenergic beta-receptors (associated with Class II effect). This causes the refractory period of atrial tissue to increase, hence its effectiveness in the treatment of atrial fibrillation and atrial flutter.

Dofetilide (Tikosyn) can also cause serious ventricular arrhythmias, primarily Torsade de pointes, a type of ventricular tachycardia associated with QT prolongation.

ATRIAL FIBRILLATION/ATRIAL FLUTTER

Dofetilide (Tikosyn) is indicated for highly symptomatic atrial fibrillation or atrial flutter (irregular heartbeats). Dofetilide (Tikosyn) has also been shown to be effective in converting the irregular heartbeats to normal rhythm. In addition, dofetilide (Tikosyn) may help maintain the normal rhythm for a longer period of time.

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)

MEDICALLY NECESSARY

I48.11 Longstanding persistent atrial fibrillation
I48.19 Other persistent atrial fibrillation
I48.20 Chronic atrial fibrillation, unspecified
I48.3 Typical atrial flutter
I48.4 Atypical atrial flutter

NOT MEDICALLY NECESSARY

I48.0 Paroxysmal atrial fibrillation

HCPCS Level II Code Number(s)
N/A

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.021b:

03/28/2025	The policy has been reviewed and reissued to communicate the Company's continuing position on dofetilide (Tikosyn®) use in the inpatient setting.
05/07/2024	This version of the policy will become effective 05/07/2024. This policy has been updated to communicate the Company's coverage positions for dofetilide (Tikosyn®) use in the inpatient setting. Therapy with dofetilide (Tikosyn®) indication has been expanded to include dose escalation and reinitiation per compendia.
09/05/2023	The policy has been reviewed and reissued to communicate the Company's continuing position on dofetilide (Tikosyn®) use in the inpatient setting.
06/01/2022	The policy has been reviewed and reissued to communicate the Company's continuing position on dofetilide (Tikosyn®) use in the inpatient setting.
05/24/2021	The policy has been reviewed and reissued to communicate the Company's continuing position on dofetilide (Tikosyn®) use in the inpatient setting.
07/15/2020	This policy has been reissued in accordance with the Company's annual review process.
10/09/2019	The policy has been reviewed and reissued to communicate the Company's continuing position on dofetilide (Tikosyn®) use in the inpatient setting.
10/01/2019	This version of the policy will become effective 10/01/2019. The following ICD-10 CM codes have been **added** to this policy: I48.11 Longstanding persistent atrial fibrillation I48.19 Other persistent atrial fibrillation I48.20 Chronic atrial fibrillation, unspecified The following ICD-10 CM codes have been **termed** from this policy: I48.1 Persistent atrial fibrillation I48.2 Chronic atrial fibrillation

Revisions From MA08.021a:

11/07/2018	This policy became effective 06/29/2016. It has been reviewed and reissued to communicate the Company's continuing position on Dofetilide (Tikosyn®) Use in the Inpatient Setting.
06/21/2017	This policy has been reissued in accordance with the Company's annual review process.
06/29/2016	This version of the policy will become effective 06/29/2016. This policy has been updated to be consistent with the US Food and Drug Administration (FDA) labeling. The following codes were removed from the policy: I48.91 I48.92.

Revisions From MA08.021:

05/27/2015	The policy has been reviewed and reissued to communicate the Company's continuing position on dofetilide (Tikosyn®) Use in the Inpatient Setting.
01/01/2015	This is a new policy.

Version Effective Date:
05/07/2024
Version Issued Date:
05/07/2024
Version Reissued Date:
03/28/2025