Clinical Policy: Insulin Icodec-abae (Awiqli)

Reference Number: CP.CPA.367
Effective Date: 06.01.26
Last Review Date: 05.26
Line of Business: Commercial

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Insulin icodec-abae (Awiqli®) is a long-acting human insulin analog.

FDA Approved Indication(s)

Awiqli is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Awiqli is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Diagnosis of type 2 diabetes mellitus;
2. Age ≥ 18 years;
3. One of the following (a or b):
   a. For California Exchange plans only: Failure of all the following, unless clinically significant adverse effects are experienced or all are contraindicated: insulin glargine-yfgn (unbranded Semglee®), Toujeo®, Tresiba®;
   b. For California and Oregon Commercial plans only: Failure of all the following, unless clinically significant adverse effects are experienced or all are contraindicated: Lantus®*, Toujeo, Tresiba.
   **For California and Oregon Commercial Plans, Lantus SoloStar (NDC 00088221901) is non-formulary. Refer to the formulary exception policy, CP.CPA.190.*

Approval duration: 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. One of the following (a or b):
   a. For California Exchange plans only: Failure of all the following, unless clinically significant adverse effects are experienced or all are contraindicated: insulin glargine-yfgn (unbranded Semglee), Toujeo, Tresiba;
   b. For California and Oregon Commercial plans only: Failure of all the following, unless clinically significant adverse effects are experienced or all are contraindicated: Lantus*, Toujeo, Tresiba.
   **For California and Oregon Commercial Plans, Lantus SoloStar (NDC 00088221901) is non-formulary. Refer to the formulary exception policy, CP.CPA.190.*

Approval duration: 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Lantus, Toujeo (insulin glargine) and insulin glargine-yfgn (unbranded Semglee)	**Type 2 diabetes mellitus**: 0.2 units/kg SC QD or 10 units/day initially. Adjust dosage according to patient response	Not applicable

Tresiba (insulin degludec)	**Type 2 diabetes mellitus**: Initiation:
	• Insulin-naïve: 10 units SC QD
	• Already on insulin: SC QD:
	  ○ Adults: same unit dose as total daily long or intermediate-acting insulin unit dose
	  ○ Pediatrics: 80% of total daily long or intermediate-acting insulin unit dose
		Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): use during episodes of hypoglycemia; hypersensitivity to insulin icodec-abae or any of the excipients in Awiqli
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Type 2 diabetes mellitus	SC once-weekly on the same day each week Initiation: • Insulin-naïve: The recommended starting dose is 70 units SC once-weekly on the same day each week. • Switching from daily basal insulin therapy: Administer the first dose of Awiqli SC on the day after the last dose of daily basal insulin. ○ **Week 1 dosage:** Multiply the previous total daily basal insulin dosage by 7, then	Not applicable

Indication	Dosing Regimen	Maximum Dose
	multiply by 1.5, and round to the nearest 10 units. ○ **Week 2 dosage:** Multiply the previous total daily basal insulin dosage by 7, and round to the nearest 10 units. ○ **Week 3 dosage and beyond:** Titrate from the previous dosage based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal. When the required dose is larger than 700 units, split the dose into two injections.	

VI. Product Availability

Single-patient-use FlexTouch prefilled pens containing 700 units/mL: 1 mL (700 units), 1.5 mL (1,050 units), 3 mL (2,100 units)

VII. References

1. Awiqli Prescribing Information. Plainsboro, NJ: Novo Nordisk; March 2026. Available at: https://awiqli.ca/en/. Accessed April 9, 2026.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.09.26	05.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.