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| Policy Name: | Tziel (teplizumab) | Policy#: | 3187P |
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Tziel (teplizumab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Tziel (teplizumab) under the specialty medical or Medicare part B benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of stage 2 type 1 diabetes at risk for progressing to clinical disease as supported by all of the following:
 - Presence of at least two positive pancreatic islet autoantibody samples within the past 6 months (examples of antibodies include glutamic acid decarboxylase 65 (GAD) autoantibody, insulin autoantibody (IAA), insulinoma-associated antigen 2 autoantibody (IA-2A), zinc transporter 8 autoantibody (ZnT8A), islet cell autoantibody (ICA).
 - Presence of abnormal blood sugar levels without always high blood sugar levels
 - Family relative with type 1 diabetes
- 1.2 Prescribed by or in consultation with an endocrinologist (hormone doctor)
- 1.3 Age 8 years or older
- 1.4 Clinical review for coverage is completed by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Type 1 diabetes stage 3
- 2.2 Type 2 diabetes

3. Approval Period

- 3.1 14-day treatment within 12 months
- 3.2 One approval per lifetime

CPT Codes

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HCPCS Codes

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| J9381 | Injection, teplizumab-mzwv, 5 mcg |
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References

1. Tziel (teplizumab) [prescribing information]. Red Bank, NJ: Provention Bio Inc; November 2022.

2. Herold KC, Bundy BN, Long SA, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. *N Engl J Med*. 2019 Aug 15;381(7):603-613.
3. Crossen S, et al. Changing costs of type 1 diabetes care among US children and adolescents. *Pediatr Diabetes*. 2020;21(4):644-648.
4. American Diabetes Association Professional Practice Committee; 3. Prevention or Delay of Diabetes and Associated Comorbidities: Standards of Care in Diabetes—2024. *Diabetes Care* 1 January 2024; 47 (Supplement_1): S158–S178.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.