

Clinical Information:

Does the patient have a clinical diagnosis of type 1 diabetes (that is, Stage 3 type 1 diabetes)? Please Note: Clinical type 1 diabetes is also referred to as Stage 3 type 1 diabetes. "Stage 1 type 1 diabetes" and "Stage 2 type 1 diabetes" are considered preclinical states and would not fall into the category of clinical type 1 diabetes. Yes No

Does the patient have type 2 diabetes? Yes No

Is documentation being provided to confirm the patient has tested positive for at least TWO of the following type 1 diabetes-related autoantibodies on two separate occasions: glutamic acid decarboxylase 65 (GAD65) autoantibody; islet antigen-2 (IA-2) autoantibody [also referred to as insulinoma-associated antigen-2 autoantibody {IA-2A}]; islet-cell autoantibody (ICA); insulin autoantibody (IAA); zinc transporter 8 (ZnT8) autoantibody? Please Note: The patient needs to have tested positive on two separate occasions, with at least two positive autoantibodies per occasion; however, the patient does not have to be positive for the same two antibodies on both occasions. For example, a positive test for GAD65 and IA-2 on one occasion, and positive test for ICA and IAA on another occasion would satisfy the requirement. PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

Is documentation being provided to confirm the patient has a 2-hour postprandial glucose level greater than or equal to 140 to less than 200 mg/dL during an oral glucose tolerance test in the preceding 2 months? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if no) Is documentation being provided to confirm the patient has a fasting plasma glucose level greater than or equal to 100 to less than 126 mg/dL in the preceding 2 months? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if no) Is documentation being provided to confirm the patient has an HbA1c greater than or equal to 5.7% to less than 6.5% in the preceding 2 months? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hematologic compromise, as defined by meeting the following: Lymphocyte count greater than or equal to 1,000 lymphocytes/mcL? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if yes) Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hematologic compromise, as defined by meeting the following: Hemoglobin greater than or equal to 10 g/dL? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if yes) Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hematologic compromise, as defined by meeting the following: Platelet count greater than or equal to 150,000 platelets/mcL? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if yes) Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hematologic compromise, as defined by meeting the following: Absolute neutrophil count greater than or equal to 1,500 neutrophils/mcL? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hepatic compromise, as defined by meeting the following: Alanine aminotransferase (ALT) less than or equal to 2 times the upper limit of normal (ULN)? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if yes) Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hepatic compromise, as defined by meeting the following: Aspartate aminotransferase (AST) less than or equal to 2 times the ULN? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this

case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

(if yes) Is documentation being provided to confirm that, at baseline (prior to the initiation of Tzield), the patient does not have evidence of hepatic compromise, as defined by meeting the following: Bilirubin less than or equal to 1.5 times the ULN? PLEASE NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include, but is not limited to chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information. Yes No

According to the prescriber, does the patient have laboratory or clinical evidence of acute infection with Epstein-Barr Virus or cytomegalovirus? Yes No

(if no) According to the prescriber, does the patient have active serious infection? Yes No

(if no) According to the prescriber, does the patient have chronic active infection (other than localized skin infection)? Yes No

Is the requested medication being prescribed by an endocrinologist? Yes No

Does the prescriber attest that the patient has not previously received Tzield?

- It is attested the patient has not previously received Tzield
 It is not attested

Additional Information:

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature: _____ **Date:** _____

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