Stem Cell Therapy Alternatives for Type 1 Diabetes: Current Progress and Limitations

Matteo Pilling

Abstract

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disease that causes a lack of insulin production by the pancreas. In the USA alone, there are around 2.1 million people affected by this condition. Patients must manage their blood sugar levels due to the lack of insulin. The standard treatment for this condition is lifelong insulin therapy. However, insulin pumps do not replace the beta cells that produce insulin and can cause problems with exercise, cost, and managing treatment. Due to this, research into stem cell therapies is being investigated. This review looks at the efficacy and safety of cell-based therapies that have been used in clinical studies for treating T1DM, including stem cell-derived islet cells and mesenchymal stem cells.

What Is T1DM and What Are Its Symptoms?

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disease characterized by the inability of pancreatic β-cells to produce sufficient levels of insulin, which can lead to hyperglycemia. Symptoms of T1DM typically develop during childhood or adolescence, but they can also develop in adulthood (Cleveland Clinic, 2026). The symptoms of T1DM include polydipsia (excessive thirst), frequent urination, extreme hunger, unexplained weight loss, fatigue, and blurred vision (Cleveland Clinic, 2026). If left undiagnosed or untreated, some may suffer from diabetes-related ketoacidosis (DKA), a life-threatening complication requiring immediate medical treatment. In the U.S., DKA accounts for over 220,000 hospital admissions per year (Ramphul & Joynauth, 2020). This results from the liver breaking down fats in the body due to a lack of insulin, resulting in the release of ketones into the bloodstream (Cleveland Clinic, 2025b). Symptoms of DKA include fruity-smelling breath, nausea and vomiting, abdominal pain, rapid breathing, confusion, and extreme tiredness (Cleveland Clinic, 2026).

Around 12% of people living in the U.S. are living with diabetes, which equates to approximately 40 million Americans (Centers for Disease Control and Prevention, 2026). T1DM

accounts for about 5-10% of diabetes cases, whereas type 2 diabetes mellitus (T2DM) makes up the remaining 90-95%. While T1DM is characterized as an autoimmune disorder that renders the pancreas unable to produce insulin, T2DM is classified by insulin resistance (i.e., insulin is produced, but muscles, fat, and liver are unable to utilize it properly; Cleveland Clinic, 2024b). This causes the pancreas to produce extra amounts of insulin to compensate for the resistance, leading to hyperinsulinemia, which is characterized by higher-than-normal amounts of insulin in the blood (Cleveland Clinic, 2024b). This, in turn, can cause prediabetes or lead to T2DM when the pancreas cannot produce enough insulin to maintain healthy blood glucose levels. T2DM typically develops much later than T1DM, with most people experiencing symptoms over the age of 45 (National Library of Medicine, n.d.-a).

Both types of diabetes require lifestyle changes oriented around maintaining healthy glucose levels. For T2DM, it is not always required to take insulin; many patients are able to regulate their glucose levels by maintaining a healthy diet or regular exercise (Cleveland Clinic, 2024b). However, all individuals with T1DM require insulin injections to maintain healthy blood glucose levels (Cleveland Clinic, 2026). Accordingly, people with T1DM must monitor their glucose levels and administer insulin injections several times per day.

Due to this being a lifelong condition that requires repetitive treatment, additional treatment options are needed. This review will explore the use of stem cell therapies as an alternative approach to treating T1DM.

Limitations of Current Treatments

Currently, the standard treatment for T1DM is lifelong insulin therapy, which is administered through insulin pumps or insulin injections. First introduced in the 1970s, insulin pumps are small, wearable battery-powered devices that deliver a regular flow of fast-acting insulin under the skin throughout the day (Cleveland Clinic, 2023). Insulin pumps are meant to replace the need for regular insulin injections. However, many insulin pumps allow for a bolus, manual surges of insulin, particularly following meals. While new innovations are being made on insulin pumps, they still have many issues that reduce the quality of life for those with T1DM. One major issue with having an insulin pump is participating in physical activities, especially high-intensity sports (Perkins & Riddell, 2006), due to the difficulty of managing insulin levels.

Exercise can cause blood glucose levels to change rapidly, increasing the risk of hypoglycemia and requiring adjustments to insulin delivery or carbohydrate intake. Additionally, physical activity can result in the damage or displacement of pumps, creating more challenges for insulin pump users. Another limitation that insulin pump users face is the cost of the treatment. Approximately 1 in 5 people with diabetes have put off getting a continuous glucose monitor or pump, with half of the people crediting it to financial strain (American Diabetes Association, n.d.-a). The cost of all of the pumps and insulin could overwhelm people depending on their healthcare insurance plan and financial situation, considering that medical equipment is expensive and that T1DM is a lifelong condition (Cleveland Clinic, 2023). Another concern with insulin pumps is their durability, as the tubing and needle are prone to being bent or kinked, which prevents the flow of insulin into the body (Cleveland Clinic, 2023). Additionally, insulin can crystallize within 2-3 days, which leads to necessary pump changes every couple of days (Cleveland Clinic, 2023).

Due to the various problems resulting from insulin pumps and a lack of alternative options, the use of stem cell therapy is being researched as a possible method to treat T1DM (Grattoni et al., 2025). Stem cells are unspecialized human cells that are self-renewing and can develop into many different specialized cell types in the body (Mayo Clinic, 2026). Stem cell therapy uses stem cells or their derivatives to repair damaged or diseased tissue or restore function to organs. Regenerative therapies are a promising emerging treatment option, especially for patients who have restrictive or no other options for treatment of a disease or illness (Mousaei Ghasroldasht et al., 2022).

There are two types of stem cell transplantation methods: autologous and allogeneic. Autologous transplantation involves using a person's own stem cells, editing them in a laboratory, and then infusing the edited cells back into the body (Dana-Farber Staff, 2019). Allogeneic transplantation uses stem cells from a donor, typically a healthy individual, to replace the dysfunctional cells in the body. In allogeneic therapy, the stem cells infused into the body can be either (1) normal, healthy stem cells intended to replace damaged cells or generate healthy replacement cells, or (2) stem cells that have been gene-edited in a laboratory to improve their function (Cleveland Clinic, 2025a). Currently, stem cell therapies are successfully being used to treat blood disorders and various cancers, but they are also being tested in patients with T1DM as well (National Cancer Institute, 2023).

Clinical Studies Using Stem Cell Therapy for T1DM

In a subset of patients with T1DM, two severe complications can occur: impaired awareness of hypoglycemia (IAH) and severe hypoglycemic events (SHEs). IAH occurs when an individual has a diminished ability to perceive the physical symptoms of hypoglycemia such as shakiness, sweating, rapid heartbeat, dizziness, sudden hunger, and tingling sensations (American Diabetes Association Professional Practice Committee for Diabetes, 2026). Because patients experiencing IAH do not detect these symptoms, they often fail to treat the drop in blood glucose levels before cognitive function is impaired (McNeilly & McCrimmon, 2018). This can lead to people seeking medical attention for hypoglycemia well after it is recommended. IAH is present in about 25% of adults with T1DM and increases an individual's chance of SHEs by up to sixfold (Baxter et al., 2024). SHEs occur when the blood sugar of a person drops so low that they become unconscious or confused, resulting in the need for medical assistance from another person (American Diabetes Association, n.d.-b). Although current treatments are effective in preventing SHEs in 50-80% of patients with IAH and SHEs, there is still a sizable number of patients at risk (Hering et al., 2016). Thus, researchers are exploring alternative treatment options to better manage IAH and SHEs

One recent study examined 48 patients who received allogeneic purified human pancreatic islet (PHPI) transplants with the goal of evaluating the effectiveness of the treatment for specific health complications stemming from insulin deficiency (Hering et al., 2016). This was a conventional donor-derived islet transplantation that aimed to achieve HbA1c < 7.0% in one year and to gain independence from SHEs after 28 days. The HbA1c test measures average blood glucose levels over the past two to three months, and typically, levels above 6.5% indicate having diabetes (National Library of Medicine, n.d.-b). This multicenter, single-arm, phase 3 study was conducted in 8 different centers in North America. The criteria for the patients in the study included: age 18-65 years, T1DM for ≥ 5 years, absent simulated C-peptide, IAH and/or marked glycemic lability, and a history of SHEs for at least 12 months (Hering et al., 2016). In the process of the pancreas creating insulin, it first starts as a larger protein called proinsulin, which splits into two parts–insulin and C-peptide–that go directly into the bloodstream (Labcorp, n.d.) Because C-peptide is a byproduct of insulin production, testing for the levels of C-peptide

in the blood or urine is an effective way to measure how much insulin your body naturally produces (Cleveland Clinic, 2022a). In this study, one of the goals was to test whether the treatment increased the levels of C-peptide, indicating insulin is being produced. Treatment effectiveness was additionally evaluated through HbA1c levels, severe hypoglycemic events, insulin requirements, insulin independence, glucose monitoring, and measures of hypoglycemia awareness (Hering et al., 2016). The PHPIs were inserted into the portal vein, and additional transplants were permitted if insulin independence was not achieved. The patients received immunosuppressive drugs to prevent graft rejection, and the 48 participants were followed for 1 year. Among all participants, the patients received a total of 75 infusions: 22 received one infusion, 25 received two, and 1 received three. Out of the 48 patients, 42 met the primary successful end point of independence from SHEs and an HbA1c < 7% at 1 year, but after 2 years, only 34 still met the requirement. Median HbA1c decreased to 5.6% at both 1 and 2 years, and measures of hyperglycemia awareness significantly improved following transplantation. However, there were still several complications and safety concerns observed in this study, including bleeding requiring transfusion in 10.4% of participants, infections related to immunosuppression in 4.1% of participants, and a significant decrease in kidney function. No study-related deaths or disabilities were reported. This clinical trial showed that PHPI transplantation is effective in treating patients with IAH and unmanageable SHEs. Despite the promising results, the single-arm design and small sample size limited the comparisons between treatments and the ability to generalize results to a larger population.

Researchers have also sought to understand what effect PHPI transplants had on health-related quality of life (HRQOL), functional health status, and health utility (Foster et al., 2018). Two surveys on HRQOL and two surveys on functional health status and health utility were distributed to these patients before and after the islet therapy at each of the following time points: 3 months prior to islet transplantation; days 75, 365, and 730 after the initial islet transplantation; and days 75, 180, 365, and 730 after the final islet transplantation. Following the initial transplant, patients reported experiencing decreased diabetes-related stress, in addition to little to no distress related to their physicians or interpersonal relationships. Moreover, patients reported experiencing less stress over time related to hyperglycemia following treatment. Their overall emotional burden also decreased over time. In regard to HRQOL, improvements were reported in physical functioning and general health. These results indicate that islet

transplantation is not only an effective treatment, but it can also improve the quality of life and health states of individuals undergoing treatment, despite the use of immunosuppressive medication, which is known to have negative side effects (Opałka et al., 2023).

Another allogeneic islet cell therapy called Zimislecel is also being investigated to treat T1DM. The phase 1-2 trial was split into 3 parts–A, B, and C–with each part evaluating different endpoints (Reichman et al., 2025). In part A, the patients received half a dose of Zimislecel initially, and then, in a two-year time frame, there was an option for the second half of the dose to be administered. The primary endpoint that Part A sought to complete was to ensure the safety of the treatment. Parts B and C included patients receiving the full dose of Zimislecel, with the main endpoints being freedom from SHEs days 90 through 365 and an HbA1c < 7.0%. The doses of Zimislecel were administered through the portal vein, and after the treatment, all patients received glucocorticoid-free immunosuppressive therapy to prevent the body from attacking the newly administered cells. The study had a total of 14 participants (2 in part A, and 12 in B and C), and they completed 12 months of follow-up and analysis. Immunosuppression created several health effects, with the most prominent, neutropenia, occurring in 3 patients. Neutropenia is a below-average level of neutrophils, a type of white blood cell made in the bone marrow, which acts as the body's main defense against bacteria and fungal infections (Cleveland Clinic, 2022b). Two patient deaths occurred but for reasons presumed to be unrelated to the trial (Reichman et al., 2025). In the 12 B and C patients, every single person reported no SHEs and had HbA1c < 7%. Ten of the patients achieved insulin independence by a year. Because this was a phase 1-2 trial, there was a small sample size of patients that has yet to be expanded upon.

Another study utilizing allogeneic stem cells to treat T1DM instead focused on investigating the effectiveness of umbilical cord mesenchymal stem cells (UC-MSCs) in treating T1DM (Lu et al., 2021). In this nonrandomized study, investigators examined whether stem cell transplantation could preserve insulin-producing β-cells. The study included 53 patients with 27 receiving 2 UC-MSC infusions and the other 26 receiving only insulin pump therapy, serving as the control population. The primary endpoint of this study was clinical remission defined as a 10% increase in baseline levels of fasting and/or postprandial C-peptide. The range of fasting C-peptide for healthy adults is 0.5-2 ng/ml while the range of fasting C-peptide for adults with T1DM is 0.3-0.6 ng/ml (Vinay et al., 2026). An increase of 10% in baseline C-peptide levels

indicates an improvement in the body's natural insulin production. After one year, nearly 41% of the participants in the treatment group achieved clinical remission, while the control group had a significantly smaller percentage of 11.5% (Lu et al., 2021). In the study, 3 participants achieved insulin independence: 2 of the 3 retained independence for over a year, and the other participant retained it for 3.8 months. There were no severe adverse effects from the treatment observed in the study, with the only negative outcome being mild fevers in 3 patients. The main drawback of this study is its limited follow-up period, which makes it difficult to determine the long-term effectiveness of the treatment.

A recent study tested the use of patient-derived (autologous) induced pluripotent stem cell (iPSC)-derived islet cell therapy as a treatment for T1DM (Wang et al., 2024). These islet cells were transplanted into a 25-year old patient with T1DM with the primary aim of reducing glycated hemoglobin (HbA1c) levels to below 7.0%, as well as testing for safety and tolerability of the treatment. A secondary aim of the study was to test whether the patient could achieve insulin independence (Wang et al., 2024). Adipose cells were collected from the patient, chemically induced into pluripotent stem cells, and then differentiated into islet cells. The islet cells were injected under the abdominal anterior rectus sheath of the patient. Within two weeks of transplantation, the patient's daily requirement for exogenous insulin began to decrease from a baseline of 54 ± 0.9 units/day, and the decline continued until the patient fully achieved insulin independence on day 75. The patient remained insulin independent throughout the one-year follow-up period. Despite the promise of this treatment, its safety and efficiency have yet to be evaluated in a larger population or over a longer period than the one-year follow-up. It is also important to note that this evidence is based on a single patient who was already on immunosuppressants due to a previous liver transplantation. Therefore, this study cannot fully determine the effects that the immunosuppressive treatment had on the results, and patients who do not already take immunosuppressants may experience different outcomes or side effects from the same islet cell transplantation therapy.

In June 2023, the FDA approved Lantidra (also known as donislecel), the first FDA-approved donor-derived islet therapy for treating T1DM. (U.S. Food and Drug Administration, 2023). Brittle T1DM is a form of T1DM that is especially difficult to manage and features unpredictable swings in blood glucose levels that cause frequent episodes of hypoglycemia and hyperglycemia, which can often disrupt daily life and lead to hospitalizations

(Cleveland Clinic, 2024a). Brittle T1DM affects approximately 0.3% of people with T1DM (Gillespie, 2025). Lantidra was tested in two clinical studies (a phase 1/2 and a phase 3 study) with a total of 30 patients with T1DM and hypoglycemic unawareness, with each patient receiving 1-3 infusions (Rios et al., 2024). Twenty-one participants achieved insulin independence for over a year following treatment: 11 participants no longer needed to take insulin for one to five years and 10 participants for more than five years (U.S. Food and Drug Administration, 2023). Of the 30 total participants, only five patients did not achieve any days with insulin independence. Some patients had adverse side effects due to the immunosuppression associated with the procedure and had to discontinue the immunosuppressive medications. This led to the loss of the islet cells as well as the inability to achieve insulin independence. Many patients experienced one or more serious negative reactions from the treatment, most commonly nausea, fatigue, anemia, diarrhea, and abdominal pain. Despite there being some adverse side effects, Lantidra demonstrated effectiveness in restoring insulin independence in the majority of patients.

Conclusion

The FDA approval of Lantidra is a major milestone for cellular therapies for treating T1DM because it demonstrated that transporting cells into a patient could remove the need for conventional insulin injection. Lantidra's approval represents progress in cell-based treatments from small-scale studies and experimental research to clinical practice. This could potentially lead to more research into cell therapies for other diseases as well. Many studies are currently investigating different forms of stem cell therapy, including the use of allogeneic islet cells (Hering et al., 2016; Reichman et al., 2025) and mesenchymal stem cells (Lu et al., 2021), as well as autologous iPSCs differentiated into islet cells (Wang et al., 2024).

There are numerous limitations to stem cell therapy that prevent its widespread usage for treatment of T1DM. These include having a limited donor supply, the need for lifelong immunosuppression, safety concerns, and engraftment limitations (Sneddon et al., 2018; Wan et al., 2022). Many allogeneic islet-cell therapies require lifelong treatment with immunosuppressive drugs. These drugs can be highly toxic and lead to many severe side

effects, including kidney dysfunction, limiting their use to more severe cases of T1DM (Hering et al., 2016; Opałka et al., 2023). Additional safety concerns include the risk of tumor formation and immunogenicity when the immune system targets the transplanted cells (Zuo et al., 2025). The engraftment of the stem cells remains a limitation due to three main factors: (1) the ability of the stem cells to survive in the patient after transplantation, (2) the ability for the stem cells to reach the damaged pancreas or target tissue following systemic injection due to the potential for the cells to get trapped by other organs, such as the liver or lungs, and (3) the potency and effectiveness of the engrafted cells (Zuo et al., 2025).

While the FDA approval of Lantidra shows that cell-based treatments can move from small-scale studies to clinical settings, its use remains limited to a select group of patients with severe symptoms and difficult-to-manage T1DM, leaving routine care out of reach for most patients (U.S. Food and Drug Administration, 2023). For stem cell therapy to become a routine option, each of the current limitations must become a goal for the field. First, the limited supply of donor islets must be overcome through renewable cell sources, as early work with Zimislecel suggests is possible (Reichman et al., 2025). Second, the need for lifelong immunosuppression must be reduced or eliminated so that the benefits can outweigh the risks for patients who don't have severe cases of T1DM (Sneddon et al., 2018; Wan et al., 2022). Third, potential safety concerns like tumor formation and immunogenicity will likely require follow-up studies in larger populations, because most of the studies to date have followed patients for less than two years (Lu et al., 2021; Reichman et al., 2025; Wang et al., 2024). Finally, improving the function and survival of transplanted cells is essential for this treatment, because these advancements could shift T1DM treatment from lifelong, burdensome insulin management into a lasting, accessible therapy. Although the field is still early, the progress that has emerged so far suggests that there is real reason for optimism.

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