Public Statement:

In an effort to modify motor disability of advanced Parkinson's disease, embryonic mesencephalic (midbrain) tissue containing dopamine-producing cells is implanted into the caudate and putamen of the candidate's brain. This procedure has been demonstrated not to improve health outcomes, and is not covered.

Medical Policy Statement:

Fetal Mesencephalic Transplantation (FMT) for the treatment of Parkinson's Disease is considered not medically necessary because it has been demonstrated to not be effective, and is not covered.

Background:

Most of the studies published between 1995 and 2001 consist of uncontrolled open trials, examining clinical outcomes in small groups of patients. As such, they lack the strength conferred by study designs with control groups, randomization, and double-blinding protocol. However, these studies report minor to moderate improvement in motor function in at least some patients in each study. Magnitude of the treatment effect, however, is variable.

There was 1 randomized controlled trial, reporting clinical outcomes for 33 patients. Clinical outcomes among these patients were variable, moderate in magnitude, and were in part affected by age. The primary outcome variable, a patient-scored global rating, showed no significant difference at 12 months after surgery between patients treated with transplantation and those undergoing sham surgery.
In an NIH study, Olanow and colleagues reported on a double-blind, placebo-controlled trial of fetal nigral (the layer of gray substance separating the tegmentum of the midbrain from the crus cerebri) transplantation in 34 patients with advanced Parkinson's disease followed prospectively for 24 months. Patients were randomized to one or four donor bilateral transplantation or a placebo procedure. The authors reported no significant differences in overall treatment effect (p = 0.244) and persistent dyskinesia in 56% of patients in the transplant group. While a treatment effect was seen in milder patients (p = 0.006), the authors concluded the results did not support fetal nigral transplantation as a recommended therapy for Parkinson's disease.

In the NINDS double-blind, placebo controlled RCT, 40 patients with Parkinson's disease were randomized to receive bilateral four donor implantation of embryonic mesencephalic cells or a placebo procedure and followed for one year. Gordon, et. al. reported patients in the NINDS trial improved significantly on reaction and movement times 12 months post transplantation (p = 0.005) while patients in the placebo group deteriorated. The authors concluded reaction time analyses can be useful in identifying subtle motor performance changes over time.

McRae and colleagues reported on a portion of the NINDS RCT that evaluated quality of life (QOL) of 30 of the 40 study patients at baseline, 4, 8, and 12 months post procedure. The authors reported a strong placebo effect, since all patients reported better scores if they believed they had received the transplant.

Trott and colleagues reported on cognition 1 year post-procedure in the NINDS study. The authors reported no significant differences in cognitive performance at follow-up for the transplant or placebo group as performance for most measures remained the same.

An evidence-based medical review update by Goetz, et al. in May 2005 concluded that fetal mesencephalic cell transplantation was non-efficacious for symptomatic control of Parkinsonism.

References:


Blunt SB, Jenner P, Marsden CD.(1992) Motor function, graft survival and gliosis in rats with 6-OHDA lesions and fetal ventral mesencephalic grafts chronically treated with L-


Fetal mesencephalic transplantation for the treatment of Parkinson’s disease. 1995 Blue Cross Blue Shield Association Technology Evaluation Center Assessment.


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Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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