DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality

Ref: QSO-24-19-OPO

DATE: August 29, 2024

TO: CMS Location Offices

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Organ Procurement Organization (OPO) Conditions for Coverage – Reporting Data Related to Pancreata Procured for Research

Memorandum Summary

- Organ Procurement Organizations (OPOs) are required to report data related to pancreata procured for research.
- Existing reporting codes were not specific enough to capture whether a pancreas was used for islet cell research.
- CMS in conjunction with Health Resources and Services Administration (HRSA) and the Organ Procurement & Transplantation Network (OPTN), developed new codes to differentiate between pancreata used for islet cell transplantation or research and pancreata used for non-islet cell research.
- Pancreata will be considered "used" for research if they are *accepted for use* in bona fide research conducted by a qualified researcher, such as those approved by the National Institutes of Health.

Background:

Organ Procurement Organizations (OPOs) are required to report data related to pancreata procured for research. Existing codes for reporting were not specific enough to capture whether a pancreas was used for islet cell research. Therefore, CMS in conjunction with HRSA and the OPTN, developed new codes to differentiate between pancreata used for islet cell transplantation or research and pancreata used for non-islet cell research (described below).

Discussion:

Pancreata will be considered "used" for research if they are *accepted for use* in bona fide islet cell research conducted by a qualified researcher, such as research approved by the National Institutes of Health.

CMS expects that OPOs will maintain documentation that the pancreas has been accepted for use in bona fide islet cell research conducted by a qualified researcher.

To facilitate the use of the new codes, the OPTN will provide reports for each OPO listing the data requiring revision. Once received, OPOs must revise and submit their 2021 and 2022 pancreata data to the OPTN within 15 business days, in addition to revising and resubmitting 2023 and 2024 data to the OPTN within 30 business days.

Once the OPOs have resubmitted 2022 pancreata data to the OPTN and the OPTN dataset is updated, CMS' analytic contractor will re-run the 2024 OPO Annual Individual Performance Reports (using updated 2022 SRTR data). CMS will provide a new preview period for the OPOs before the 2024 aggregate performance report is published.

Pancreata Data Entry
OPTN reason code 510 (recovered for research) paired with disposition 4 (recovered not for transplant), and reason code 505 (recovered for transplant; submitted for research) paired with disposition 5 (recovered for transplant, but not transplanted), were not specific enough to capture whether a pancreas was "used" for islet cell research. Therefore, the OPTN developed pancreata codes for OPO use under dispositions 4 and 5 as follows:

Disposition 4 – Recovered not for transplant

517- Recovered for Research: Sent for non-islet cell research
518- Recovered for Research: Accepted for islet cell research

Disposition 5 – Recovered for transplant, not transplanted

524- Recovered for Transplant: Sent for non-islet cell research
525- Recovered for Transplant: Accepted for islet cell research

Disposition 6 – Organ transplanted (pancreas/islet cells) - **No Change**

Contact:
For questions or concerns relating to this memorandum, please contact QSOG_OPO@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff immediately.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

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- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.

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