FDA Releases Draft Guidance for Industry: Homologous Use of Human Cells, Tissues, and Cellular and Tissue Based Products

The FDA has released a new draft guidance document entitled ‘Homologous Use of Human Cells, Tissues, and Cellular and Tissue Based Products’ dated October 2015. The guidance provides tissue establishments with the definition of homologous use and how to apply the regulatory criterion to their HCT/Ps.

Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor (21 CFR 1271.3(c)), including when such cells or tissues are for autologous use. FDA considers an HCT/P to be for homologous use when it is used to repair, reconstruct, replace, or supplement:

- Recipient cells or tissues that are identical (e.g., skin for skin) to the donor cells or tissues, and perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor; or,
- Recipient cells that may not be identical to the donor’s cells, or recipient tissues that may not be identical to the donor’s tissues, but that perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor.

The FDA then provided examples of the basic function of different HCT/Ps and clarified that a corneal graft is considered homologous use.

3-2. The basic functions of the cornea include protecting the eye by forming its outermost layer and serving as the refracting medium of the eye. A corneal graft is transplanted to restore sight in a patient with corneal blindness. This is homologous use because a corneal graft performs the same basic functions in the donor as in the recipient.
FDA to Hold a Public Hearing on HCT/P Guidance Documents

The FDA has scheduled a 1-day public hearing to obtain input on four recently issued draft guidance documents relating to the regulation of human cells, tissues, or cellular or tissue-based products (HCT/Ps). The public hearing will be held on April 13, 2016, from 8 a.m. to 5 p.m. at FDA's White Oak Campus, Silver Spring, MD. Persons seeking to attend or to present at the public hearing must register by January 8, 2016.

The four draft guidance documents include:

- A new draft document entitled Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff has been released. The full notice can be found here, and the draft guidance here.
- The comment period has been reopened for the draft document Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry previously announced in the Federal Register on October 23, 2014. The draft guidance can be found here.
- The comment period has been reopened for the draft document Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff, previously published in the Federal Register on December 23, 2014. The draft guidance can be found here.
- The comment period has been reopened for the draft document Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry, previously published in the Federal Register on December 24, 2014. The draft guidance can be found here.

Electronic or written comments will be accepted after the public hearing until April 29, 2016.

EBAA will attend the public hearing in April and submit formal comments to the FDA on behalf of our members and transplantation partners. Members are invited to submit their feedback to Jennifer@restoresight.org no later than April 1, 2016 so they can be integrated into our remarks. Members may also submit their own comments to the FDA.

CMS Finalizes CY 2016 OPPS/ASC Payment System and Excludes Separate Payment for Non-transplant Corneas

The Centers for Medicare & Medicaid Services (CMS) has finalized the Calendar Year 2016 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System policy changes and payment rates.
ASC Payment Update

- Under the CY 2016 OPPS/ASC final rule, ASC payments are annually updated for inflation based on a percentage increase in the Consumer Price Index for all urban consumers (CPI-U). Additionally, the Medicare statute applies a multifactor productivity (MPF) adjustment to the ASC annual update. For CY 2016, the CPI-U update is 0.8 percent, and the MPF adjustment is 0.5 percent, resulting in an MFP-adjusted CPI-U update factor of 0.3 percent.
- CMS finalized the CY 2015 ASC conversion factor ($44.058) wage adjustment budget neutrality factor of 0.9997 in addition to the MFP-adjusted CPI-U update factor of 0.3%, which results in a CY 2016 ASC conversion factor of $44.177 for ASCs meeting the quality reporting requirements. ASCs not meeting the quality reporting requirements have a quality reporting/MFP-adjusted CPI-U update factor of -1.7%, which results in a proposed CY 2016 ASC conversion factor of $43.296.
- Under the final rule, Ambulatory Payment Classification groups are being restructured. CMS reorganized and consolidated several APCs across all nine clinical APC families. CMS is finalizing the restructure with modifications in response to public comments.
- CMS did not propose any new measures for the ASC Quality Reporting Program, but requested comments on two possible future measures: Normothermia Outcome and Unplanned Anterior Vitrectomy. ASCs are subject to a 2 percentage point reduction in their annual payment updates if they do not meet ASCQR Program requirements.

Decrease in OPPS payments

- Under the final rule for 2016, there is a net decrease in OPPS payments of 0.4 percent. CMS said it estimates total OPPS payments for 2016 will decrease by approximately $13.3 million compared to the year prior, excluding estimated changes in enrollment, utilization and case mix.
- The decrease for 2016 is attributable to a 2 percentage point reduction to the OPPS conversion factor. The reduction is intended to account for CMS' overestimation of the amount of packaged laboratory payments under the OPPS for laboratory tests and other budget neutrality adjustments, according to the rule.

Corneal Tissue

For CY 2016, CMS limited the separate payment policy for corneal tissue acquisition costs in the hospital outpatient department and ASC to only corneal tissue that is used in a corneal transplant procedure. In the ASC, CMS finalized including corneal tissue procurement as a covered ancillary service only when it is integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure, and will pay separately for this service under the ASC payment system.
This means that CMS will not make separate payment for corneal tissue when used in any non-transplant procedure. Therefore, CMS is requiring packaged payment for all tissues used as patch grafts in glaucoma shunt surgery. CMS believes that the total payment for the procedure described by HCPCS 66180 (with corneal tissue, sclera, or pericardium packaged) is adequate when procedures are performed in both the HOPD and the ASC.

CMS will provide a specific list of corneal transplant procedure HCPCS codes with which HCPCS code V2785 may be reported in the January 2016 OPPS and ASC updates, but specifically mentioned the following CPT codes:

- 65710 (Keratoplasty (corneal transplant); anterior lamellar);
- 65730 (Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia));
- 65750 (Keratoplasty (corneal transplant); penetrating (in aphakia));
- 65755 (Keratoplasty (corneal transplant); penetrating (in pseudophakia));
- 65756 (Keratoplasty (corneal transplant); endothelial);
- 65765 (Keratophakia);
- 65767 (Epikeratoplasty); and
- any successor code or new code describing a new type of corneal transplant procedure that uses eye banked corneal tissue.

This document is scheduled to be published in the Federal Register on 11/13/2015 and available online at [http://federalregister.gov/a/2015-27943](http://federalregister.gov/a/2015-27943).

**FDA Releases New Search Tool**

The FDA’s new search tool enables users to search the Agency’s growing list of over 3000 guidance documents quickly and efficiently. This search feature covers the entire FDA organization – drugs, devices, biologics, etc.

**FDA and OHRP Release Guidance on IRB Meeting Minutes**

The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) have issued draft guidance titled, “Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs". This draft guidance is intended for institutions and IRBs responsible for oversight of human subject research under FDA and HHS regulations. This joint draft guidance is now available on FDA's website at [http://www.fda.gov/RegulatoryInformation/Guidances/ucm470046.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm470046.htm), and OHRP’s website at [http://www.hhs.gov/ohrp/newsroom/rfc/index.html](http://www.hhs.gov/ohrp/newsroom/rfc/index.html).
This joint draft guidance is intended to assist institutions and IRBs responsible for preparing and maintaining minutes of IRB meetings. The draft guidance describes requirements for minutes and provides recommendations for meeting the regulatory requirements for minutes.

Comments are due by January 4, 2016.