ISBT 128
PRODUCT CODE SELECTION
FOR CELL THERAPY PRODUCTS

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PRODUCT CODE SELECTION

Session Outline and Objectives:

1. **Background**
   - Review Resource Information
   - Review the terminology to better understand product descriptions
   - Review concepts to better understand product code selection

2. **Discuss Scenarios**
   - Review examples of product descriptions for product code selection

3. **Q & A**
   - Address questions from the audience
PRODUCT CODE SELECTION

Resource Information:

• ICCBBA Website:
  ᵇhttp://www.iccbba.org

• Cellular Therapy Homepage:
  ᵇhttp://www.iccbba.org/cellulartherapy_home.html
PRODUCT CODE SELECTION

Resource Information:


• IG-036 Revised Cellular Therapy Terminology v1.0.0 August 2013
  ➢ Contains the Crosswalk Attachment

• IG-022 Use of Product Code Data Structure 003-Cellular Therapy v1.1.0 August 2013
PRODUCT CODE SELECTION

3 Cellular Therapy

Important Note: The terms and definitions represented in this section were developed in 2012-2013. Products labeled prior to the introduction of this terminology and coding system were defined using a different coding system. See Chapter 12 for definitions of these codes. The document Implementation Guide, Revised Cellular Therapy Terminology (2013) provides information about the transition from previously used codes and definitions to those currently used.

3.1 Class
Class names are in the format type of cells, comma, source of cells.

3.1.1 Subcategories of Classes
Cellular therapy products are divided into two class name subcategories.

Subcategory 1:
- At collection the product code will describe the composition of the cell therapy products. It can be HPC, NC, or MNC. These products can be collected for direct infusion without further manipulation. HPCs may be further manipulated, but would retain the class name HPC if they are used as a source of hematopoietic progenitor cells. If these products undergo modification such as cryopreservation and thawing, the class will not change but the modification is added into the product description as an attribute.

Subcategory 2:
- After enumeration or manufacture/processing of the collected products, the product may be identified by the target cell population. These class names are based on desired cell population thought to present in the product.
Use of the Product Code
[Data Structure 003]
Cellular Therapy
Version 1.1.0
August 2013
PRODUCT CODE SELECTION

Use of Product Code [Data Structure 003] - Cellular Therapy

• Section 2: Product Code
• Section 3: Product Description Code
• Section 4: Donation Type Code
• Section 5: Division Code
PRODUCT CODE SELECTION

Product Code: 8 Characters Long

S11804A0

S1180  Product Description Code
(5 Character)

4  Donation Type Code
(1 Character)

A0  Division Code [00 at collection]
(2 Character) * >26 divisions – see: IG Use of Product Divisions
[Data Structure 032]
PRODUCT CODE SELECTION

1. Introduction
2. Changed Class Names
3. Changes to Definitions of Classes
4. Modifiers Converted to Attributes
5. New Attributes to Support Elimination of Modifiers
6. Attributes Moved or Retired from the Manipulation Group
7. Replacements for TC-T Cells Product Description Codes
8. Product Description Code Retirement
9. Crosswalk Old Product Descriptions to New Product Descriptions
PRODUCT CODE SELECTION

What is the key?
PRODUCT CODE SELECTION

Understand the definitions of the terms used to describe a product.
PRODUCT CODE SELECTION

Product Description Code

• Class
  ▪ Subcategory 1
  ▪ Subcategory 2

• Attribute
  ▪ Core Conditions (Mandatory)
  ▪ Groups (Optional Variables)
PRODUCT CODE SELECTION

• Class
  ▪ Two Subcategories, both employ a comma
  ▪ Definitions were changed to establish a common format for defining classes.
  ▪ Format: “Type of Cells, Source of Cells”
    Example: NC, MARROW (Subcategory 1)
    MSC, MARROW (Subcategory 2)
PRODUCT CODE SELECTION

• Class: Subcategories
  ▪ Subcategory 1: (Collection)
    ➢ At collection the product code will describe the composition of the cell therapy products.
    ➢ HPC, NC or MNC
    ➢ These products can be collected for direct infusion without further manipulation.
    ➢ HPCs may be further manipulated, but would retain the class name HPC if they are used as a source of hematopoietic progenitor cells.

Examples: HPC, APHERESIS
NC, MARROW
MNC, APHERESIS
PRODUCT CODE SELECTION

• Class: Subcategories
  ▪ Subcategory 2: (After Manufacture, Enumeration)
    ➢ After enumeration or manufacture / processing of the collected products, the product may be identified by the target cell population.
    ➢ These class names are based on desired cell population thought to be present in the product.
  
  Example: MSC, MARROW
            T CELLS, APHERESIS
PRODUCT CODE SELECTION

• Modifiers
  - Eliminated as an individual concept
  - Converted to Attributes
    Consistent with tissue terminology
    Allows for growth within the database structure
PRODUCT CODE SELECTION

Modifiers ➔ Attributes

• Mobilization
  ▪ Mobilized and Non-Mobilized
    The terms were removed from class definitions and are now terms in the Attribute Group - Mobilization.

• Pooled Single Donor
  ▪ The term was part of a class name and was used in the class definition. Pooled is now Pooled Single Donor in the Attribute Group - Pooled Single Donor.

• Cryopreserved
  ▪ The term was a modifier and is now in the Attribute Group - Modification
PRODUCT CODE SELECTION

• Attributes:
  - Core Conditions
    (Anticoagulant/Volume/Temperature)
  - Groups and Variables

New Groups as well as Variables within the groups were created.
# PRODUCT CODE SELECTION

## Attribute Groups

<table>
<thead>
<tr>
<th>Group Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Describes the expected use of the product.</td>
</tr>
<tr>
<td>Manipulation</td>
<td>Describes processing applied to a product other than to enrich or reduce a cell population.</td>
</tr>
<tr>
<td>Preparation — Cryoprotectant</td>
<td>Active cryoprotectant in the product.</td>
</tr>
<tr>
<td>Preparation — Blood Component from Third Party Donor</td>
<td>Describes blood products from other donors used during processing, such as albumin, Fresh Frozen Plasma, AB serum, Red Blood Cells.</td>
</tr>
<tr>
<td>Preparation – Other Additives</td>
<td>Describes additives introduced other than as part of the anticoagulant solution at the time of collection.</td>
</tr>
<tr>
<td>Genetically Modified</td>
<td>Cells which have been modified by the insertion of exogenous genetic material.</td>
</tr>
<tr>
<td>Irradiation</td>
<td>Indicates whether or not the product has been irradiated.</td>
</tr>
<tr>
<td>Modification</td>
<td>Processing that changes the cellular milieu and maintains the integrity of the target cell population.</td>
</tr>
<tr>
<td>Mobilization</td>
<td>Indicates whether or not an agent was administered to the donor/patient to increase the yield of target cells collected.</td>
</tr>
<tr>
<td>Pooled Single Donor</td>
<td>Indicates whether or not the product is a combination of multiple collections of the same product type from the same donor or aliquots of the same collection.</td>
</tr>
<tr>
<td>Cultured</td>
<td>Indicates whether or not cells have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additives.</td>
</tr>
<tr>
<td>Enrichment</td>
<td>Provides information on processing to enrich cell population</td>
</tr>
<tr>
<td>Reduction</td>
<td>Provides information on processing to reduce cell population or plasma</td>
</tr>
</tbody>
</table>
PRODUCT CODE SELECTION

Attribute Group: Intended Use

Describes the expected use of the product.

• 4 Options (currently)
  ▪ Default: For Administration
    For patient use: The product is intended for administration to patients.

This does not mean the product has been released.
PRODUCT CODE SELECTION

Attribute Group: Preparation – Cryoprotectant

Active cryoprotectant in the product

• 8 Options (currently)
  ▪ Default: No Cryoprotectant
    No cryoprotectant has been added.

Options for cryoprotectant include concentration not specified in coding.
PRODUCT CODE SELECTION

Attribute Group: Mobilization

Indicates whether or not an agent was administered to the donor/patient to increase the yield of target cells collected.

• 3 Options
  ▪ Default: Not Specified
    Mobilization is not specified in the coding.

*Mobilization is no longer assumed in definitions and should be specified when applicable.
PRODUCT CODE SELECTION

Attribute Group: Pooled Single Donor

Indicates whether or not the product is a combination of multiple collections of the same product type from the same donor or aliquots of the same collection.

• 2 Options
  ▪ Default: Not Specified
    Information about product pooling is not specified in the coding.
PRODUCT CODE SELECTION

Attribute Group: Modification

Processing that changes the cellular milieu and maintains the integrity of the target cell population.

• 5 Options (currently)
  ▪ Default: Not Specified
    Modifications are not specified in the coding.
PRODUCT CODE SELECTION

Attribute Group: Manipulation

• The Manipulation Attribute Group was divided into four groups by creating three new ones.
  ▪ Manipulation
  ▪ Enrichment
  ▪ Reduction
  ▪ Cultured
Attribute Group: Manipulation

Describes processing applied to a product other than to enrich or reduce a cell population.

• 6 Options (currently)
  - Default: Not Specified
    No information about processing is specified in this Attribute group.
FAQ:

• Should I select “Filtered” for my bone marrow at collection?
  
  ▪ The bone marrow harvest procedure includes a series of filters to obtain the collected product. This is not considered a separate manipulation step.
  
  ▪ Select “Filtered” if an independent filtration is performed. (Ex. In laboratory, using a 170 - 260 micron filter)
PRODUCT CODE SELECTION

Attribute Group: Enrichment

Provides information on processing to enrich cell population.

• 12 Options (currently)
  ▪ Default: Not Specified
    No information about cell enrichment is specified in the coding.
PRODUCT CODE SELECTION

Attribute Group: Reduction

Provides information on processing to reduce cell population or plasma.

• 10 Options (currently)
  ▪ Default: Not Specified
    No information about cell or plasma reduction is specified in the coding.
FAQ:
• How do I select RBC and Plasma Reduced for my product description?
• Where is the volume reduced option to describe my concentrated product?

Review the Definitions
FAQ:

• How do I select RBC and Plasma Reduced for my product description?
  ▪ Select “Buffy coat enriched” from the Enrichment Group.

• Definition: Buffy coat enriched
  ▪ Cells remaining after reduction of mature erythrocytes and plasma.
PRODUCT CODE SELECTION

Attribute Groups: Enrichment / Reduction

FAQ:

• Where is the volume reduced option to describe my concentrated product?
  - Select “Plasma Reduced” from the Reduction Group.

• Definition: Plasma reduced
  - The cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation.
PRODUCT CODE SELECTION

Attribute Group: Cultured

Indicates whether or not cells have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additives.

• 2 Options
  ▪ Default: Cultured: No
    Product was not cultured.
PRODUCT CODE SELECTION

Attribute Group: Irradiation

Indicates whether or not the product has been irradiated.

- 2 Options
  - Default: Irradiation: No
    - Product was not irradiated.
Attribute Group: Genetically Modified

Cells which have been modified by the insertion of exogenous genetic material.

• 2 Options
  ▪ Default: Genetically modified: No
    Not genetically modified.
PRODUCT CODE SELECTION

Attribute Group: Preparation – Blood Component from Third Party Donor

Describes blood products from other donors used during processing such as albumin, Fresh Frozen Plasma, AB Serum, Red Blood Cells.

- 2 Options
  - Default: 3rd Party Comp: No
    No third party blood component added.
PRODUCT CODE SELECTION

Attribute Group: Preparation – Blood Component from Third Party Donor

FAQ:

• Do I use this attribute group if I make cryoprotectant solution (freeze mix) with Human Serum Albumin?
  ▪ Yes, HSA is a 3rd Party Blood Component
PRODUCT CODE SELECTION

Attribute Group: Preparation – Other Additives

Describes additives present in the product.

• 5 Options (currently)
  ▪ Default: Other Additives: No
    No additives other than as part of the anticoagulant solution at the time of collection.
PRODUCT CODE SELECTION

Attribute Group: Preparation – Other Additives

Describes additives present in the product.

- 5 Options
  - Default: Other Additives: No
  - Concurrent Plasma
  - Concurrent Plasma + Other
  - Other additives present
  - Other additives including animal source
FAQ:

• Do I use this attribute group if my product is diluted?
  ▪ Yes
  “Diluted” was removed from the Manipulation group to eliminate redundancy in coding.
FAQ:

- Do I request a new option within this group to identify my specific additive? Example: Saline
  - No, Other additives present – means “Other additives present”.

  The specific type of additive is not specified in coding but is identified in the accompanying labeling information.
PRODUCT CODE SELECTION

Attribute Group: Preparation – Other Additives

FAQ:

• Do I use this attribute group if I make the cryopreservation solution (freeze mix) with Normasol, Plasma-Lyte or another electrolyte solution?
  ▪ Yes, select attribute “Other additives present”
PRODUCT CODE SELECTION

Attribute Group: Preparation – Other Additives

FAQ:

• If I dilute my product with concurrent plasma and add an animal source product during processing, may I select both attributes?

  ▪ No, You may select one option for each attribute group. Select the option that is the most important to identify in coding.

  “Other additives including animal source”
PRODUCT CODE SELECTION

Points To Remember:

• You are not required to select an attribute variable from each of the 13 attribute groups.
  ▪ Core Attributes are required. (May not be specified in code.)
  ▪ You may not specify more than one variable for each attribute group.

• Default will vary with attribute group.
  ▪ Default is not always “Not Specified”
PRODUCT CODE SELECTION

Points To Remember:

• “See Accompanying Documentation”
  ▪ Not all information can be captured in coding.

• Not all processing steps need to be captured in product coding.
  ▪ Just because you perform a process doesn’t mean you need to code for that process.
### PRODUCT CODE SELECTION

Product descriptions are listed in a very structured way in the Product Description Codes Database.

- The characters that separate each term (Class, Attribute Core Conditions, and Attribute Variables) are consistent.

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1150</td>
<td>HPC, CORD BLOOD</td>
</tr>
<tr>
<td>S1154</td>
<td>HPC, APHERESIS</td>
</tr>
</tbody>
</table>
PRODUCT CODE SELECTION

Examples
Walk through some selections together
PRODUCT CODE SELECTION

Examples:

- **HPC, MARROW**
  - Collected Product
  - Final Product

- **HPC, APHERESIS**
  - Collected Product
  - Final Product
PRODUCT CODE SELECTION

Examples:

- MNC, APHERESIS
  - Collected Product
- T CELLS, APHERESIS
  - Final Product
- NC, WHOLE BLOOD
  - Collected Product
- T CELLS, WHOLE BLOOD
  - Final Product
PRODUCT CODE SELECTION

Example: HPC, MARROW - Collected Product

Class: HPC, MARROW (Subcategory 1)

Attribute: Core Conditions
Heparin (Anticoagulant)
XX (Volume)
rt (Storage Temperature)

Attribute: Groups & Variables
Not Specified in Coding

S1152 HPC, MARROW|Heparin/XX/rt
Question:
Does the volume on the label include the anticoagulant / harvest media?
Yes,
Total Volume = Total Volume in the bag
PRODUCT CODE SELECTION

Example: HPC, MARROW - Collected Product

Class: HPC, MARROW (Subcategory 1)

Attribute: Core Conditions

Citrate (Anticoagulant)
XX (Volume)
refg (Storage Temperature)

Attribute: Groups & Variables

Not Specified in Coding

S1136 HPC, MARROW|Citrate/XX/refg
PRODUCT CODE SELECTION

Example: HPC, MARROW - Final Product
Class: HPC, MARROW (Subcategory 1)
Attribute: Core Conditions Heparin/XX/≤-120C
Attribute: Groups & Variables

- 10 % DMSO (Preparation Cryoprotectant)
- 3rd Party Comp: Yes (Preparation – 3rd Party Donor)
- Other Additives: Yes (Preparation – Other Additive)
- Cryopreserved (Modification)
- Buffy Coat Enriched (Enrichment)

S1517 HPC, MARROW|Heparin/XX/<=-120C|10% DMSO|3rd Party Comp:Yes|Other Additives:Yes|Cryopreserved|Buffy coat enriched
PRODUCT CODE SELECTION

Example: HPC, APHERESIS - Collected Product

Class: HPC, APHERESIS (Subcategory 1)

Attribute: Core Conditions
Citrate (Anticoagulant)
XX (Volume)
refg (Storage Temperature)

Attribute: Groups & Variables
Mobilized (Mobilization)

S1128 HPC, APHERESIS|Citrate/XX/refg|Mobilized
PRODUCT CODE SELECTION

Example: HPC, APHERESIS - Final Product
Class: HPC, APHERESIS (Subcategory 1)
Attribute: Core Conditions Citrate/XX/≤-150°C
Attribute: Groups &Variables
  10 % DMSO (Preparation Cryoprotectant)
  3rd Party Comp: Yes (Preparation – 3rd Party Donor)
  Other Additives: Yes (Preparation – Other Additive)
  Cryopreserved (Modification)
  Mobilized (Mobilization)
  Plasma Reduced (Reduction)

S1446 HPC, APHERESIS|Citrate/XX/<=-150C|10% DMSO|3rd Party Comp:Yes|Other Additives:Yes|Cryopreserved|Mobilized|Plasma reduced
PRODUCT CODE SELECTION

Example:  MNC, APHERESIS - Collected Product

Class:  MNC, APHERESIS (Subcategory 1)

Attribute:  Core Conditions
            Citrate  (Anticoagulant)
            XX  (Volume)
            refg  (Storage Temperature)

Attribute:  Groups & Variables
            Non-mobilized  (Mobilization)

S1226  MNC, APHERESIS|Citrate/XX/refg|Non-mobilized
PRODUCT CODE SELECTION

Example: T CELLS, APHERESIS - Final Product

Class: T CELLS, APHERESIS (Subcategory 2)

Attribute: Core Conditions  Citrate/XX/≤-150°C

Attribute: Groups & Variables

5 % DMSO (Preparation Cryoprotectant)
3rd Party Comp: Yes (Preparation – 3rd Party Donor)
Other Additives: Yes (Preparation – Other Additive)
Cryopreserved (Modification)

S2131 T CELLS, APHERESIS|Citrate/XX/≤-150°C|5% DMSO|3rd Party Comp: Yes|Other Additives: Yes|Cryopreserved
PRODUCT CODE SELECTION

Example: NC, WHOLE BLOOD - Collected Product

Class: NC, WHOLE BLOOD (Subcategory 1)

Attribute: Core Conditions
Heparin (Anticoagulant)
XX (Volume)
rt (Storage Temperature)

Attribute: Groups & Variables
Not Specified in Coding

S1284 NC,WHOLE BLOOD|Heparin/XX/rt
PRODUCT CODE SELECTION

Example: T CELLS, WHOLE BLOOD - Final Product
Class: T CELLS, WHOLE BLOOD (Subcategory 2)
Attribute: Core Conditions Heparin/XX/≤ -150°C
Attribute: Groups &Variables
  5 % DMSO (Preparation Cryoprotectant)
  3rd Party Comp: Yes (Preparation – 3rd Party Donor)
  Other Additives: Yes (Preparation – Other Additive)
  Cryopreserved (Modification)

S2132 T CELLS, WHOLE BLOOD|Heparin/XX/<=-150C|5% DMSO|3rd Party Comp:Yes|Other Additives:Yes|Cryopreserved
PRODUCT CODE SELECTION

Points to Remember / Consider:

- You do not need to code for intermediate products.
- You may use local codes for situations specific to your facility.
PRODUCT CODE SELECTION

Points to Remember / Consider:

• You do not need to specify a variable for each of the 13 Attribute Groups.
• You may not specify more than one variable for each of the 13 Attribute Groups.
• You should be aware of the default for each Attribute Group.
PRODUCT CODE SELECTION

Points to Remember / Consider:
There are new class names for T Cells
• T Cells, Apheresis
• T Cells, Cord Blood
• T Cells, Marrow
• T Cells, Whole Blood

❖ You may not collect a Subcategory 2 Class Product
PRODUCT CODE SELECTION

Points to Remember / Consider:

• Every manipulative step performed does not need to be included in product coding.
• Resources are available to help you.
PRODUCT CODE SELECTION

Product Description Code Lookup Program

Overview

This program allows you to search for product description codes.

Must be logged on to view the program

Product Description Code Lookup Program

Download the program here, 4MB

After installing the Product Lookup Program Version 3, you will have to download three Text files from the ICCBBA website into the same folder that the program is saved in on your computer. These Text files are listed on the ICCBBA website as:

1) Text - Attribute
2) Text - Class
3) Text - Product Description

When saving these Text files, use the default file names given to them:

1) attribute
2) class
3) productdescription

For further information on how to use this program see our basic factsheet entitled "Product Code Selection" in the "ISBT 128 Basics" section or click here.

*DO NOT OPEN MULTIPLE SCREENS WHEN USING THE LOOKUP PROGRAM!

If the search window containing drop down menus and the product description code search feature are open simultaneously they will not yield results.

* The lookup program is not compatible with MacOS
PRODUCT CODE SELECTION

Cellular Therapy Product Description Code Request Form

Form for use by facilities making requests to the ICCBBA office. Please see instructions here.

- Facility Identification Number
- Contact Name
- Contact Email Address
- Component Class: CONCURRENT PLASMA, APHESIS
- Anticoagulant Type: Citrate
- Volume: XX
- Storage Temperature: Refg
- Intended Use: Default: For administration
- Manipulation: Default: Not specified
- Preparation: Cryoprotectant: Default: No Cryoprotectant
- Preparation: Blood Component From Third Party Donor: Default: 3rd party comp: NO
- Preparation: Other Additives: Default: Other additives: No
- Genetically Modified: Default: Genetically Modified: No
- Irradiation: Default: Irradiation: No
- Modification: Default: Not specified
- Mobilization: Default: Not specified
- Pooled Single Donor Group: Default: Not specified
- Cultured: Default: Cultured: No
- Enrichment: Default: Not specified
- Reduction: Default: Not specified

Submit to ICCBBA  Reset
RESOURCE CONTACTS

• ICCBBA Website:
  - http://www.iccbba.org

• Cellular Therapy Homepage:
  - http://www.iccbba.org/cellulartherapy_home.html

• ICCBBA Office:
  - iccbba@iccbba.org
Thank You

Contact Information:
 Leigh Sims Poston
 leigh.poston@yahoo.com
Product Code Selection

Q & A Time