MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
BONE MARROW TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (BMTSAC) MEETING

Thursday, March 14, 2019

South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order

Co-Chairpersons Stella and Uberti called the meeting to order at 9:47 a.m.

A. Members Present:

Philip J Stella, MD, Co-Chairperson – Trinity Health – Michigan
Joseph Uberti, MD, Co-Chairperson – McLaren Health Care
Tricia Baird, MD FAAFP MBA – Priority Health
Ishmael A. Jaiyesimi, MS, DO, FACP – Beaumont Hospital – Royal Oak
Daniel Lebovic, MD – Ascension Michigan
Edward M. Peres, MD – Henry Ford Health System (arrived at 9:53 a.m.)
Natalie Pirkola – Ford Motor Company
Gordan Srkalovic, MD, PhD, FACP – Sparrow Health System
Burton Vanderlaan MD – BCBSM
Stephanie Williams, MD – Spectrum Health Systems
Gregory A. Yanik, MD, BS – University of Michigan Health System

B. Members Absent:

Synnomon Harrell – International Union, UAW

C. Michigan Department of Health and Human Services Staff present:

Tulika Bhattacharya
Marcus Connolly
Beth Nagel
Tania Rodriguez

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review and Approval of Agenda

Motion by Dr. Williams, seconded by Dr. Baird to accept the agenda as presented. Motion carried.

IV. Review and Approval of February 14, 2019 Minutes

Motion by Ms. Prikola, seconded by Dr. Srkalovic to accept the minutes as presented. Motion carried.

V. Overview and Discussion of CMS Proposal

Co-Chairpersons Uberti and Stella reviewed the CMS proposal.

Discussion followed.

VI. Overview of the Foundation for the Accreditation of Cellular Therapy (FACT) Accreditation Requirements for Immune Therapies

Co-Chairperson Uberti provided an overview of FACT accreditation requirements. (Attachment A)

Discussion followed.

VII. Continued Discussion of Charge

There was continued discussion of the charge.

Discussion followed.

VIII. Next Steps

Review proposed draft language

IX. Future Meeting Dates

April 18, 2019, May 16, 2019, June 20, 2019, and July 17, 2019.

X. Public Comment

Arlene Elliott – Arbor Advisors
Bret Jackson – Economic Alliance for Michigan

XI. Adjournment

Motion by Dr. Baird, seconded by Ms. Pirkola to adjourn the meeting at 11.20 a.m. Motion carried.

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Wayne State University

SAC –Meeting
CART Cell Therapy
3/14/19

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

Proposed Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)

2/15/19-30 Day Public Comment Period Begins

- CMS proposes to cover autologous treatment with T-cells expressing at least one chimeric antigen receptor (CAR) through coverage with evidence development (CED) when prescribed by the treating oncologist, performed in a hospital, and all of the following requirements are met

Hospital Requirements

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- Cellular Therapy Program consisting of an integrated medical team
- Clinical Program Director, a Quality Manager, and at least one physician experienced in cellular therapy
- Demonstrates that protocols, procedures, quality management, and clinical outcomes are consistent from regular interaction among all team members
- Designated care area that protects the patient from transmission of infectious agents and allows for appropriate patient isolation as necessary for evaluation and treatment
- Written guidelines when administering CAR T-cell therapy for patient communication, monitoring, and transfer to an intensive care unit

Requirements for Treatment Criteria

- If the patient is administered CAR T-cell therapy in the inpatient hospital setting, then the patient must be enrolled in, and the furnishing hospital is participating in, a prospective, national, audited registry that consecutively enrolls patients, accepts all manufactured products, follows the patient for at least two years, adheres to the standards of scientific integrity and relevance to the Medicare population as identified in section A.4 of this decision

- If the patient is administered CAR T-cell therapy in the outpatient hospital setting, then the patient must be enrolled in, and the furnishing hospital is participating in, a prospective, national, audited registry that consecutively enrolls patients, accepts all manufactured products, follows the patient for at least two years, adheres to the standards of scientific integrity and relevance to the Medicare population as identified in section A.4

CED Questions

- How do patient outcomes compare to either the pivotal clinical trial(s) (i.e., the clinical trial(s) that served as the basis for FDA approval of the biological and/or for the FDA indication) of the biological or a cohort of controls receiving standard of care treatment?
- How do the clinical characteristics of registry patients compare to the pivotal clinical trial(s)?
- How do the clinical characteristics of registry patients affect the clinical endpoints relative to those in the pivotal clinical trial(s)?
- How does the patient report their symptom function health-related quality of life changes

Registries

- Registries must be reviewed and approved by CMS. Potential registry sponsors must submit all registry documentation to CMS for approval including the written executable analysis plan and auditing plan. CMS will review the qualifications of candidate registries to ensure that the approved registry follows standard data collection practices and collects data necessary to evaluate the patient outcomes specified above. The registry's National Clinical Trial number must be recorded on the claim.

- To this end, the authors recommend standardization through FACT or the Joint Accreditation Committee ISCT-European Society for Blood and Marrow Transplant, and discussed the importance of metrics to document the effectiveness of interventions as a basis for further improvement.

Medicare- Decision Summary

- Coverage is proposed for both the inpatient and outpatient hospital settings. Standards we would expect to find in a Cellular Therapy Program are included in the Foundation for the Accreditation of Cellular Therapy (FACT) Common Standards for Cellular Therapies (2015) and Standards for Immune Effector Cell Administration (2016) and describe quality management guidelines to incorporate performance data, as well as policies and procedures that address risk management of operations. These standards require a quality management program at the site of performance that establishes, maintains, monitors, and implements improvements in quality, process, and performance. The basis for FACT accreditation is documented compliance with the current edition of the applicable standards set. We believe adherence to criteria consistent with a nationally accredited Cellular Therapy Program promotes patient safety, and ensures best patient outcomes and optimal CAR T-cell therapy administration. We note that FACT accreditation, which considers these criteria, is also consistent with current practice by CAR T-cell manufacturers and participating hospitals involved with the administration of CAR T-cell therapy and care of patients. The data used for the FDA BLA approval were generated under safe study conditions. Therefore, to maintain the safety for beneficiaries to experience similar improvements in health outcomes overall, practitioner and provider criteria are listed in section I of this document. (Page 51-52)

Foundation For The Accreditation of Cellular Therapy (FACT)

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- Immune Effector Cells Accreditation Manual
- Fist Edition 1.1: 357 Pages

3 Major sections

- Clinical Program Standards
- Collection Standards
- Processing Facility Standards

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

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PART B CLINICAL PROGRAM STANDARDS

COLLECTION STANDARDS

PROCESSING FACILITY STANDARDS

Objectives

- ***The major objective of the FACT Standards for Immune Effector Cells is to promote quality practice in immune effector cell administration. These Standards apply to immune effector cells used to modulate an immune response for therapeutic intent, such as dendritic cells, natural killer cells, T cells, and B cells. This includes, but is not limited to, genetically engineered chimeric antigen receptor T cells (CAR-T cells) and therapeutic vaccines.***

Objectives

The scope of the Standards includes donor selection and management, administration of cells, management of adverse events, and evaluation of clinical outcomes. The Standards require a quality management (QM) program that establishes, maintains, monitors, and implements improvements in the quality of facilities, processes, and performance. These Standards are intended to be flexible to accommodate various models of patient care and use of cellular therapy products. Requirements for programs that administer immune effector cells on a unit that is not already FACT-accredited are contained fully in the FACT Immune Effector Cell Standards. When immune effector cells are administered on a FACT-accredited blood and marrow transplant (BMT) unit, the program must fully comply with the FACT-JACIE Hematopoietic Cell Therapy Standards. The additional requirements for immune effector cells are incorporated into the Hematopoietic Cell Therapy Standards also.

Objectives

These Standards were prepared with the understanding that some programs will not be responsible for collection and processing of immune effector cells. Regardless of where the cells are collected or processed, the program must meet clearly defined responsibilities for chain of custody, storage, verification of product identity, and management of adverse events. A program that is responsible for collection of cells, manufacturing of the cellular therapy product, or preparation of the product for administration must also meet the collection and processing standards detailed in Sections C and D of this document.

Standards

B1.5 The Clinical Program shall administer cellular therapy products to a minimum of five (5) new recipients during the twelve (12) month period immediately preceding accreditation and to a minimum average of five (5) new recipients per year within the accreditation cycle.

- ***Explanation:***

Clinical Programs treating patients with immune effector cell products may be participants in clinical trials using investigational products manufactured under IND, or may be administering licensed products according to clinical indications. The stand-alone immune effector cell program must meet the required number of five new patients per 12 month period to be eligible for accreditation. To be eligible for initial accreditation for immune effector cell therapies in conjunction with an HPC transplantation program, the Clinical Program must have treated at least one such patient. In addition, all other standards applicable to these cells must be met, including any risk evaluation and mitigation strategies (REMS) designated by the manufacturer.