MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR IMMUNE EFFECTOR CELL THERAPY (IECT) SERVICES

(BY AUTHORITY CONFERRED ON THE CON COMMISSION BY SECTION 22215 OF ACT NO. 368 OF THE PUBLIC ACTS OF 1978, AS AMENDED, AND SECTIONS 7 AND 8 OF ACT NO. 306 OF THE PUBLIC ACTS OF 1969, AS AMENDED, BEING SECTIONS 333.22215, 24.207, AND 24.208 OF THE MICHIGAN COMPILED LAWS.)

SECTION 1. APPLICABILITY

SEC. 1. THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL TO INITIATE, REPLACE OR ACQUIRE IECT SERVICES UNDER PART 222 OF THE CODE. THE CON COMMISSION ADDED IECT SERVICES AS A COVERED CLINICAL SERVICE PURSUANT TO MCL 333.22215. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION 22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

SECTION 2. DEFINITIONS

Sec. 2. (1) AS USED IN THESE STANDARDS:

(a) "CERTIFICATE OF NEED COMMISSION" OR "COMMISSION" MEANS THE COMMISSION CREATED PURSUANT TO SECTION 22211 OF THE CODE, BEING SECTION 333.22211 OF THE MICHIGAN COMPILED LAWS.

(b) “CHIMERIC ANTIGEN RECEPTOR (CAR) T CELLS” MEANS A GENETICALLY MODIFIED T CELL USED IN IMMUNE EFFECTOR CELL THERAPY (IECT).

(c) "CODE" MEANS ACT NO. 368 OF THE PUBLIC ACTS OF 1978, AS AMENDED, BEING SECTION 333.1101 ET SEQ. OF THE MICHIGAN COMPILED LAWS.

(d) "DEPARTMENT" MEANS THE MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS).

(e) "DEPARTMENT INVENTORY OF IECT SERVICES" MEANS THE LIST MAINTAINED BY THE DEPARTMENT OF: (i) THE IECT SERVICES OPERATING PURSUANT TO A VALID CON ISSUED UNDER PART 222; AND (ii) IECT SERVICES THAT ARE NOT YET OPERATIONAL BUT HAVE A VALID CON ISSUED UNDER PART 222. THE LIST SHALL SPECIFY THE SITE AT WHICH THE IECT SERVICE IS AUTHORIZED.

(f) "EXISTING IECT SERVICE," MEANS ANY OF THE FOLLOWING: (I) AN IECT SERVICE LISTED ON THE DEPARTMENT INVENTORY, (II) A PROPOSED IECT SERVICE UNDER APPEAL FROM A FINAL DECISION OF THE DEPARTMENT, OR (III) A PROPOSED IECT SERVICE THAT IS PART OF A COMPLETED APPLICATION UNDER PART 222 (OTHER THAN THE APPLICATION UNDER REVIEW) FOR WHICH A PROPOSED DECISION HAS BEEN ISSUED AND WHICH IS PENDING FINAL DECISION.

(g) “IMMUNE EFFECTOR CELL THERAPY (IECT)” OR “CELLULAR THERAPY” MEANS CELLULAR IMMUNOTHERAPIES, AND OTHER TYPES OF BOTH AUTOLOGOUS AND ALLOGENEIC CELLS DERIVED FROM IMMUNE EFFECTOR CELLS TO TREAT CERTAIN THERAPEUTIC INDICATIONS. FOR PURPOSES OF CON, THIS TERM DOES NOT INCLUDE THERAPEUTIC CANCER VACCINES REGULATED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) OR ADOPTIVE IMMUNOTHERAPEUTIC PRODUCTS THAT ARE CURRENTLY FDA APROVED AND ARE GIVEN TO PATIENTS IN THE OUTPATIENT SETTING, AS THESE STANDARDS PRODUCTS HAVE DIFFERENT MECHANISMS OF ACTION AND THEREFORE THESE STANDARDS SHALL NOT APPLY.

(h) “IMMUNE EFFECTOR CELL THERAPY SERVICE” OR “IECT SERVICE” MEANS THE INFUSION OR TRANSFER OF IMMUNE EFFECTOR CELLS AND/OR IMMUNE EFFECTOR CELL

THERAPIES INTO PATIENTS. THIS DEFINITION DOES NOT INCLUDE BONE MARROW OR STEM CELL TRANSPLANTATION.

(i) “IMMUNE EFFECTOR CELLS” MEANS CELLS FROM THE HUMAN BODY THAT HAVE DIFFERENTIATED INTO A FORM CAPABLE OF MODULATING OR EFFECTING AN IMMUNE RESPONSE SUCH AS, BUT NOT LIMITED TO, B CELLS, DENDRITIC CELLS, NATURAL KILLER CELLS, AND T CELLS. THIS DEFINITION INCLUDES CAR T CELLS. FOR PURPOSES OF THESE STANDARDS, IMMUNE EFFECTOR CELLS TO BE USED IN IECT SERVICES MUST BE COLLECTED AND PROCESSED AT A FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ACCREDITATED FACILITY.

(j) "INSTITUTIONAL REVIEW BOARD" OR "IRB" MEANS AN INSTITUTIONAL REVIEW BOARD AS DEFINED BY PUBLIC LAW 93-348 WHICH IS REGULATED BY TITLE 45 CFR 46.

(k) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 42 U.S.C. 1396 TO 1396G AND1396I TO 1396U.

(2) THE DEFINITIONS OF PART 222 SHALL APPLY TO THESE STANDARDS.

SECTION 3. REQUIREMENTS TO INITIATE AN IECT SERVICE

Sec. 3. INITIATE AN IECT SERVICE MEANS TO BEGIN OPERATION OF AN IECT SERVICE AT A SITE THAT DOES NOT PROVIDE IECT SERVICES AND IS NOT LISTED ON THE DEPARTMENT INVENTORY AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT. AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL DEMONSTRATE THE FOLLOWING REQUIREMENTS.

(1) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL AGREE TO OBTAIN FACT ACCREDITATION FOR IECT WITHIN 3 YEARS OF CON APPROVAL. THE APPLICANT SHALL ALSO AGREE TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF THE SERVICE.

(2) AN APPLICANT SHALL SPECIFY THE FACT ACCREDITED SITE AT WHICH THE IECT SERVICE WILL BE PROVIDED.

(3) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL CERTIFY THAT IT WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED PROTOCOLS.

SECTION 4. REQUIREMENTS FOR APPROVAL – ACQUISITION OF AN IECT SERVICE

SEC 4. ACQUISITION OF AN IECT SERVICE MEANS THE ACQUISITION (INCLUDING PURCHASE, LEASE, DONATION, OR OTHER ARRANGEMENT) OF AN EXISTING IECT SERVICE. AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING IECT SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(1) THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF THE SERVICE.

(2) THE APPLICANT AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

SECTION 5. REQUIREMENTS TO REPLACE IECT SERVICES

SEC. 5. REPLACEMENT OF AN IECT SERVICE MEANS RELOCATING AN EXISTING IECT SERVICE TO A NEW GEOGRAPHIC LOCATION. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING IECT SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING.

(1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE THAT THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE TO OBTAIN FACT ACCREDITATION, AND THE NEW SERVICE SHALL MEET THE REQUIREMENTS OF SECTION 3.

(2) THE EXISTING IECT SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE IECT SERVICE SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.

SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION

SEC. 6. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.

SECTION 7. PROJECT DELIVERY REQUIREMENTS TERMS OF APPROVAL FOR ALL APPLICANTS

SEC. 7. AN APPLICANT SHALL AGREE THAT, IF APPROVED, THE IECT SERVICE SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL:

(1) COMPLIANCE WITH THESE STANDARDS. AN APPLICANT SHALL IMMEDIATELY REPORT TO THE DEPARTMENT ANY CHANGES IN THE IECT SERVICE THAT MAY AFFECT ITS ABILITY TO COMPLY WITH THESE STANDARDS.

(2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

(a) THE APPLICANT SHALL OBTAIN FACT ACCREDITATION WITHIN 3 YEARS OF CON APPROVAL AND SHALL MAINTAIN FACT ACCREDITATION THROUGHOUT THE LIFE OF THE SERVICE AS LONG AS THE SERVICE PROVIDES CELLULAR THERAPIES FOR WHICH FACT ACCREDITATION IS REQUIRED OR RECOMMENDED. THE APPLICANT SHALL IMMEDIATELY NOTIFY THE DEPARTMENT IF IT'S FACT ACCREDITATION IS SUSPENDED, REVOKED, EXPIRED OR OTHERWISE LIMITED.

(b) AN APPLICANT SHALL CERTIFY THAT IT WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FDA APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED PROTOCOLS.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

(A) THE IECT SERVICE SHALL ACCEPT REFERRALS FOR IECT SERVICES FROM ALL APPROPRIATELY LICENSED HEALTH CARE PRACTITIONERS.

(B) THE IECT SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(C) THE IECT SERVICE SHALL NOT DENY IECT SERVICES TO ANY INDIVIDUAL BASED ON ABILITY TO PAY OR SOURCE OF PAYMENT.

(D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE IECT SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

(a) THE APPLICANT SHALL PARTICIPATE IN A DATA COLLECTION NETWORK ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY INCLUDE, BUT IS NOT LIMITED TO, ANNUAL BUDGET AND COST INFORMATION, DEMOGRAPHIC AND DIAGNOSTIC INFORMATION, PRIMARY AND SECONDARY DIAGNOSES, LENGTH OF STAY, THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES, AND OTHER DATA REQUESTED BY THE DEPARTMENT AND APPROVED BY THE CON COMMISSION. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON AN INDIVIDUAL BASIS FOR EACH DESIGNATED FACT ACCREDITED SITE; IN A FORMAT ESTABLISHED BY THE DEPARTMENT; AND IN A MUTUALLY AGREED UPON MEDIA. THE DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE RECORDS.

(b) THE IECT SERVICE SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(5) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

SECTION 8. DEPARTMENT INVENTORY OF IECT SERVICES

SEC. 8. THE DEPARTMENT SHALL MAINTAIN, AND PROVIDE ON REQUEST, A LISTING OF THE DEPARTMENT INVENTORY OF IECT SERVICES.

SECTION 9. EFFECT ON PRIOR POLICIES; COMPARATIVE REVIEWS

SEC. 10. (1) PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.