

1 MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

2
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS**
4 **FOR IMMUNE EFFECTOR CELL THERAPY (IECT) SERVICES**
5

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

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11 **SECTION 1. APPLICABILITY**

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13 SEC. 1. THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL TO INITIATE,
14 REPLACE OR ACQUIRE IECT SERVICES UNDER PART 222 OF THE CODE. THE CON
15 COMMISSION ADDED IECT SERVICES AS A COVERED CLINICAL SERVICE PURSUANT TO MCL
16 333.22215. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1)
17 OF THE CODE BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION
18 22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.
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20 **SECTION 2. DEFINITIONS**

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

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

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

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

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

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

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

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

52 (h) "IMMUNE EFFECTOR CELL THERAPY SERVICE" OR "IECT SERVICE" MEANS THE
53 INFUSION OR TRANSFER OF IMMUNE EFFECTOR CELLS AND/OR IMMUNE EFFECTOR CELL

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

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

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

65 (k) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT.
66 620, 42 U.S.C. 1396 TO 1396G AND 1396I TO 1396U.

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68 (2) THE DEFINITIONS OF PART 222 SHALL APPLY TO THESE STANDARDS.
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70 **SECTION 3. REQUIREMENTS TO INITIATE AN IECT SERVICE**

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72 Sec. 3. INITIATE AN IECT SERVICE MEANS TO BEGIN OPERATION OF AN IECT SERVICE AT
73 A SITE THAT DOES NOT PROVIDE IECT SERVICES AND IS NOT LISTED ON THE DEPARTMENT
74 INVENTORY AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT. AN
75 APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL DEMONSTRATE THE FOLLOWING
76 REQUIREMENTS.
77

78 (1) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL AGREE TO OBTAIN
79 FACT ACCREDITATION FOR IECT WITHIN 3 YEARS OF CON APPROVAL. THE APPLICANT SHALL
80 ALSO AGREE TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF
81 THE SERVICE.
82

83 (2) AN APPLICANT SHALL SPECIFY THE FACT ACCREDITED SITE AT WHICH THE IECT
84 SERVICE WILL BE PROVIDED.
85

86 (3) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL CERTIFY THAT IT
87 WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FOOD AND DRUG ADMINISTRATION (FDA)
88 APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE
89 CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS
90 OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL
91 OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED
92 PROTOCOLS.
93

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

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96 SEC 4. ACQUISITION OF AN IECT SERVICE MEANS THE ACQUISITION (INCLUDING
97 PURCHASE, LEASE, DONATION, OR OTHER ARRANGEMENT) OF AN EXISTING IECT SERVICE.
98 AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING IECT SERVICE SHALL DEMONSTRATE
99 THE FOLLOWING:
100

101 (1) THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE
102 TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF THE
103 SERVICE.
104

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

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108 **SECTION 5. REQUIREMENTS TO REPLACE IECT SERVICES**
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110 SEC. 5. REPLACEMENT OF AN IECT SERVICE MEANS RELOCATING AN EXISTING IECT
111 SERVICE TO A NEW GEOGRAPHIC LOCATION. THE TERM DOES NOT INCLUDE THE
112 REPLACEMENT OF AN EXISTING IECT SERVICE AT THE SAME SITE. AN APPLICANT
113 REQUESTING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE EACH OF THE
114 FOLLOWING.
115

116 (1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING IECT SERVICE SHALL
117 DEMONSTRATE THAT THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL
118 AGREE TO OBTAIN FACT ACCREDITATION, AND THE NEW SERVICE SHALL MEET THE
119 REQUIREMENTS OF SECTION 3.
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121 (2) THE EXISTING IECT SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT
122 LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.
123

124 (3) THE IECT SERVICE SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO
125 BEGINNING OPERATION AT THE NEW SITE.
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127 **SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION**
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129 SEC. 6. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN
130 APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL
131 CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT
132 WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.
133

134 **SECTION 7. PROJECT DELIVERY REQUIREMENTS TERMS OF APPROVAL FOR ALL APPLICANTS**
135

136 SEC. 7. AN APPLICANT SHALL AGREE THAT, IF APPROVED, THE IECT SERVICE SHALL BE
137 DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL:
138

139 (1) COMPLIANCE WITH THESE STANDARDS. AN APPLICANT SHALL IMMEDIATELY
140 REPORT TO THE DEPARTMENT ANY CHANGES IN THE IECT SERVICE THAT MAY AFFECT ITS
141 ABILITY TO COMPLY WITH THESE STANDARDS.
142

143 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

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

150 (b) AN APPLICANT SHALL CERTIFY THAT IT WILL ONLY OFFER CELLULAR THERAPIES
151 THAT HAVE FDA APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL
152 TRIAL. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED
153 PRODUCTS OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE
154 CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB
155 APPROVED PROTOCOLS.
156

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

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

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

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

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

168
169 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

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

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

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

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187 **SECTION 8. DEPARTMENT INVENTORY OF IECT SERVICES**

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

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192 **SECTION 9. EFFECT ON PRIOR POLICIES; COMPARATIVE REVIEWS**

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

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