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Perspective

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# Expanding access to CAR T cell therapies through local manufacturing

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**Table S1 Turnaround time for manufacturing of commercial autologous CAR T cells**

| Product | Targeted turnaround time (manufacturer) | Reported turnaround time (literature or pivotal trials) | Reported failure rates |
|---|---|---|---|
| Tisagenlecleucel (kymriah) | 22 days[1] | 26 days[2] | 4%[3] |
| Axicabtagene ciloleucel (Yescarta) | 16 days [4] | 27 days[4] | 1%[5] |
| Brexucabtagene autoleucel (Tecartus) | 15 days[6] | 15 days (11-28 days)[6] | 4%[6] |
| Lisocabtagene maraleucel (Breyanzi) | 24 days[7] | 24 days[8] | 10%[8] |
| Ciltacabtagene autoleucel (Carvykti) | 32 days[9] | 29 days (28-33 days)[10] | 18%[11] |
| Idecabtagene vicleucel (ABECMA) | 33 days[12] | 33 days (26-49 days)[12] | 1.5%[13] |


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13. https://www.fda.gov/media/147055/download

**Table S2: Current regulatory frameworks for approving immune effector cell products by different health regulatory authorities**

| | United States | European Union | United Kingdom | Japan | Australia | Canada |
|---|---|---|---|---|---|---|
| **Health regulatory agency** | FDA | EMA | MHRA | Pmda | TGA | Health Canada |
| **Standard marketing approval** | Yes | Yes | Yes | Yes | Yes, with exceptions | Yes |
| **Non-standard marketing approval** | • Accelerated approvals | • Conditional approval<br>• Exceptional circumstances | • Conditional approval<br>• Exceptional circumstances | • Conditional and term-limited approval | • Provisional approval | • Notice of compliance with conditions (noc/c) |
| **Special access programs** | • Expanded access<br>• Right to Try Act<br>• Humanitarian Use device | • Hospital exemption<br>• Compassionate use<br>• Named patient use | • Early access to medicines scheme (EAMS) | • Clinical research and medical practice under the Act on the Safety of Regenerative Medicine (ASRM) | • Special access schemes | • Special access program (SAP) |
| **Expedited programs** | • Priority review | • Accelerated assessment | • Accelerated assessment | • Priority review | • Priority review | • Priority Review |
| **Regulatory Tools** | • Regenerative Medicine Advanced Therapy (RMAT) Designation<br>• Orphan designation<br>• Fast track<br>• Breakthrough designations | • Advanced Therapy Medicinal Product (ATMP) classification<br>• Orphan designation<br>• Prime scheme | • Advanced Therapy Medicinal Product (ATMP) classification<br>• Orphan designation<br>• Promising innovative medicine (PIM) designation<br>• Innovative licensing and access pathway (ILAP) | • Orphan designation<br>• Sakigake-Designation | • Orphan designation | |