Exa-cel and Lovo-cel:
Final Policy Recommendations

August 21, 2023

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the July 27, 2023 CTAF public meeting on the use of lovo-cel and exa-cel for the treatment of sickle cell disease. At the meeting, ICER presented the findings of its revised report on these treatments and the CTAF voting council deliberated on key questions related to their comparative clinical effectiveness, potential other benefits and contextual considerations, and long-term value for money at current prices. Following the votes, ICER convened a Policy Roundtable of two patients, two clinical experts, two payers, and two representatives from pharmaceutical manufacturers to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Dr. Steven Pearson, MD, MSc, President of ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

All Stakeholders

All stakeholders have a responsibility to ensure equitable and optimal patient access to gene therapies for sickle cell disease (SCD) (i.e., lovo-cel and exa-cel).

Stakeholder groups, including patients and clinicians, told us that standards of care for SCD are often sub-optimal and due to a multitude of factors including, but not limited to: stigma, bias, lack of sub-specialists, and transportation. Thus, it is particularly important that all stakeholders take steps to facilitate access to potential cures for SCD in a way that does not exacerbate the health inequities (e.g., by race, geography, health literacy) that characterize the US health care system. But the focus on equitable access should not be isolated to emerging gene therapies. It is likely that gene therapies will only be accessible through Centers of Excellence. Steps should be taken by all stakeholders to ensure that all patients living with SCD have access to multidisciplinary care through these Centers that takes a broad view of the needs of patients and their families for services such as mental health and social support.

Policymakers and life science companies should also note that, while SCD is still considered a rare disease in the US (affecting approximately 100,000 people), the global prevalence and burden of disease with SCD is much higher. Unfortunately, current incentives and business models for innovation will not make it easy for the vast majority of the world to access potentially curative (and life-changing) gene therapies. Lack of global equity in both research and clinical care is an urgent ethical challenge in public health that can only be addressed by all stakeholders working together.

To address these concerns:

<u>Manufacturers should take the following actions:</u>

- Even though potentially curative gene therapies should and will command a high price, pricing still drives many access challenges, and manufacturers should price new gene therapies for SCD at the lower range of cost-effective pricing, particularly during the early years after launch when considerable uncertainty remains regarding the safety and long-term durability of benefits with treatment.

- Manufacturers should work with SCD treatment centers (e.g., Centers of Excellence) and payers to ensure that people living with SCD who are eligible and interested in gene therapy have reasonable access to it, including considerations regarding non-English speaking patients, the need for travel, coverage for ancillary care, and out-of-pocket financial burden.

- If there are geographic regions poorly served by Centers of Excellence, the manufacturer should work with clinical experts, patient advocacy groups, and others to expeditiously expand sites where gene therapy can be obtained.

- Seek to engage with other life science companies and international policymakers to perform industry-wide actions that can make transformative gene therapies available to lower income countries in a fashion that maintains incentives for innovation.

Payers should take the following actions:

- Coverage for gene therapy should be provided in a comprehensive fashion, including coverage for travel, ancillary care pre- and post-procedure (including mental health care), fertility preservation, and out-of-pocket financial burden. All elements must be addressed and aligned in order to reduce the risk that introduction of gene therapies for SCD will create new health equity concerns within a population that has had to bear many years of historical and ongoing discrimination.

Clinical specialty societies should take the following actions:

- Specialty societies should develop evidence-based guidelines and care pathways to help facilitate the delivery of optimal care for SCD. These professional groups should prepare immediately to produce updated guidelines that can guide understanding among payers and others of how to integrate these new treatments into care in an equitable fashion. Stigma, bias, and structural racism still perpetuate sub-optimal care and it is imperative that clinical societies play in role in mitigate their negative impacts.

- Specialty societies should also develop best practices around shared medical decision-making in order to facilitate meaningful patient access to a therapy that has a high likelihood of benefit, but still significant uncertainty around risks. Shared decision-making should also be done in such a way that it does not exacerbate disparities through attention to health literacy and incorporation of cultural competencies into provider trainings and patient-facing materials.

Payers

Recommendation 1

Given that there is insufficient evidence at present to distinguish between the safety or effectiveness of lovo-cel and exa-cel, and that clinical experts see no clinical reasons to favor one of the therapies for certain patient subgroups, payers may consider negotiating a lower price by covering only one of the two therapies. However, payers considering this coverage approach should be aware of important access and patient preference issues that may outweigh the benefit of achieving a lower price.

Although lovo-cel and exa-cel use different methods of gene therapy, if they both receive FDA approval with currently known evidence, there appears to be no clinical reason that both therapies

need to be routinely covered if payers wish to negotiate for lower prices by excluding one therapy from coverage. This kind of aggressive formulary management can in some cases produce large reductions in net prices, a cost reduction that would not directly benefit SCD patients but which would contribute to moderating insurance premiums (or tax payments) for the entire health system. Nonetheless, there are important factors that would suggest that payers should opt for covering both therapies. First, it is possible that some SCD Centers of Excellence themselves will decide to offer only one of the therapies, potentially complicating access for patients should their insurance plan not cover the gene therapy provided by their current specialist or the specialist nearest their home. Second, individual patients may have strong preferences for one particular method of gene therapy, with some patients potentially favoring the approach that does not insert new DNA (exa-cel), whereas other patients may prefer the approach with a longer track record (lovo-cel). In this context, sensitivity around patients being "forced" to use only the single approach covered by their insurer should be an important consideration for all payers. Finally, the evidence on these two therapies will be evolving rapidly, heightening the risks that new evidence would quickly render any coverage exclusion obsolete.

Recommendation 2

If the announced prices for lovo-cel and exa-cel align with expected patient benefits and be set toward the lower edge of their estimated cost-effectiveness ranges, payers should use the FDA label as the guide to coverage policy without narrowing coverage by including specific clinical trial restrictions unrelated to the likelihood of benefit from treatment.

Although lovo-cel and exa-cel have strong evidence of substantial *short-term* net health benefit, given the existence of alternative first-line curative therapy for some patients (i.e., HSCT) and uncertainty around longer-term safety and durability, it is reasonable for payers to use prior authorization as a component of coverage. Prior authorization criteria should be based on the FDA label, clinical evidence, specialty society guidelines, and input from clinical experts and patient groups. Coverage for therapies with prices set in fair alignment with the benefits for patients should not be restricted by including requirements not in the FDA label unless these requirements were part of the clinical trial eligibility and are required to assure that patients are not unreasonable candidates for treatment from a clinical perspective. The process for prior authorization should be clear and efficient for providers and patients. Options for specific elements of coverage criteria within insurance coverage policy are discussed below.

Recommendation 3

Since patients will need coverage for therapies that will only be accessible in specific medical centers, payers should design coverage policies that can support travel for patients and their families to receive therapy. Geographical and income constraints should not undermine the tenets of fair access to which all patients have a fundamental right.

Recommendation 4

Payers should cover fertility preservation in concert with coverage of gene therapies. Both patient stakeholders and clinical experts noted that future fertility is a key consideration in management. There are many complex issues regarding fertility (e.g., prepubescent patients, ongoing storage). Payers must be pro-active and transparent about what will be covered.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy: see Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals.

- If an initial request for coverage is denied, access to a peer-to-peer call should be rapid. In many clinicians' experience, gaining access to peer-to-peer discussion is onerous. Peer-to-peer calls facilitate the communication of individual patients' unique clinical characteristics and need for therapy. The physician peer should be knowledgeable in the management of SCD.

Drug-Specific Coverage Criteria

Coverage Criteria: Eligibility and Exclusion Criteria

- **Diagnosis:** It is reasonable for plans to include documentation of an eligible genotype in coverage criteria. Genotype corresponds well with degree of phenotypic severity. Genotypes eligible for the pivotal trials were βS/βS, βS/β0, and βS/β+ for lovo-cel, and βS/βS and βS/β0 for exa-cel. Clinical experts argued that βS/β+ patients can have severe phenotype and therefore this genotypic variant should be considered reasonable to cover for treatment with both gene therapies. Because of adverse events in patients with co-occurring alpha-thalassemia, it is reasonable and expected that these patients will be excluded from eligibility.

- **Age:** Payers will follow any labelled age restrictions for lovo-cel and exa-cel. If the FDA includes an age restriction, it seems likely that they will limit treatment to patients aged 12 or older, consistent with the clinical trial criteria. Trials are ongoing for both gene therapies among younger patients (ages 2 – 12). Even before potential expansion of an initial label to include younger children, clinical experts suggested that they would be likely to identify patients under aged 12 whose families desire gene therapy before further organ damage can occur, so payers will need to consider exceptions and actively monitor the evolving evidence base on younger pediatric patients. Alternatively, payers may adopt a broader age range for coverage and delegate decisions regarding appropriate patient selection to clinical experts at Center of Excellences.

- **Severity of SCD:** Following clinical trial eligibility language, the FDA is likely to approve gene therapies for patients with "severe" SCD, however the FDA may or may not define severity beyond noting the specific genotypic variants included. If the FDA does not include its own definition of severity, payers are likely to use clinical trial eligibility criteria related to the number and severity of vaso-occlusive events or crises (VOEs/VOCs) to define a threshold needed for coverage.

  Different definitions of VOEs and VOCs were used in the pivotal trials for the two gene therapies (see Table 1 below). Both trials used a two-year look-back period but stipulated slightly different numbers (e.g. four severe VOEs over two years vs. two VOCs per year over two years). If payers choose to use these thresholds in coverage, they should minimize the documentation burden by allowing clinician attestation. But neither definition is preferred by the clinical experts participating in the policy roundtable. These experts were concerned that any definition would be arbitrary and may exclude some patients for whom gene therapy would be very advisable given the nature of a smaller number or frequency of VOEs/VOCs. An example presented by one of the clinical experts participating in the policy roundtable was a pediatric patient with SCD and a history of stroke who now is undergoing chronic lifelong exchange transfusions, which additionally prevents VOCs/VOEs. Clinical experts felt this patient would be an ideal candidate for gene therapy but would not meet the technical specifications of the severity threshold in the clinical trials. The hope was also expressed that patients who choose to self-manage their VOEs at home despite great pain should not be denied coverage because they do not use the ER often enough to qualify.

  Therefore, as noted earlier, payers should consider the tradeoffs of adopting the specific clinical trial eligibility criteria in coverage versus an approach that relies on clinician discretion when these treatments are delivered at specialized SCD Centers of Excellence.

Table 1. Definitions of Primary Study Outcomes

	exa-cel CLIMB-121[1]	lovo-cel HGB 206[2]
VOC/VOE	Not defined/measured in trial	VOE is defined as an episode of acute pain with no medically determined cause other than a vaso-occlusion and included acute episodes of pain, ACS, acute hepatic sequestration, acute splenic sequestration, and acute priapism
Severe VOC/VOE	Severe VOC is defined as any one of the following: • Acute pain event that requires a visit to a medical facility and administration of pain medications (opioids or IV NSAIDs) or RBC transfusions • ACS, as indicated by presence of new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever • Priapism lasting >2 hours • Splenic sequestration	Severe VOE is defined as any one of the following: • A visit to a hospital or ED that exceeded 24 hours • At least 2 visits to day unit or ED during a 72-hour period (with both visits requiring IV treatment) • Priapism episode lasting more than 2 hours and leading to a medical-facility visit

ACS: acute chest syndrome, ED: emergency department, IV: intravenous, NSAID: non-steroidal anti-inflammatory drug, RBC: red blood cell, VOC: vaso-occlusive crisis, VOE: vaso-occlusive event

- **Availability of HSCT:** Clinical trial eligibility required that patients not have accessibility to a sibling-matched HSCT as first-line therapy. HSCT also offers a potential cure for SCD and has a far longer clinical track record. Clinical experts suggested that the new gene therapies would offer the advantage of avoiding immunosuppression over the longer term, but that most clinicians today would view a sibling-matched HSCT as a reasonable option prior to considering gene therapy. Attestation that a patient does not have a willing matched donor should suffice for coverage of gene therapy.

- **Appropriate usual care with hydroxyurea:** Hydroxyurea is the bedrock of appropriate usual care for patients with SCD, and the clinical trials required that patients have severe SCD while being treated with hydroxyurea. Clinical experts did not view it as unreasonable for payers to require attestation that patients have experienced inadequate control of VOE/VOCs while being treated with hydroxyurea.

- **Exclusion criteria**: Within the list of exclusion criteria for entry into the clinical trials, clinical experts emphasized that history of stroke should not be included as an exclusion for insurance coverage. Patients with a history of stroke were excluded from the clinical trials most likely to reduce the risk of short-term adverse events that could be difficult to ascribe to treatment as opposed to the underlying condition, but clinical experts argued that these patients are at high risk for further strokes and therefore have substantial opportunity to benefit from gene therapy.

Manufacturers

Recommendation 1

Manufacturers should align prices with independent estimates of the patient-centered therapeutic value of their treatments, and in the context of significant uncertainty regarding longer-term safety and durability of benefits, prices should be set at the lower end of a reasonable cost-effectiveness range.

New potentially curative therapies for SCD bring the promise of considerable short-term as well as lifetime benefit, but there also remains substantial uncertainty regarding longer-term safety and the durability of benefits. Pricing at launch should reflect the estimated lifetime benefits of treatment, including broader benefits to patients along their life course, but in the context of this heightened uncertainty, manufacturers should seek to price new treatments at the lower range of cost-effective pricing until additional real-world evidence is available.

Recommendation 2

Although equitable access to gene therapy for SCD can improve racial health equity, manufacturers should not inflate pricing to account for this value. If anything, lower pricing will produce fewer access challenges for health systems and patients, and manufacturers should share in the social responsibility to make these treatments available and affordable.

While society gives priority and assigns value to therapies that reduce disparities[3], this value above and beyond the direct health benefits of treatment should not be translated into higher prices and profits for manufacturers. Society's appreciation of the value of reducing disparities should translate into additional funding for at-risk communities themselves.

Recommendation 3

In the context of high-impact single or short-term therapies, transparent consideration should be given to a pricing scenario that "shares" any substantial cost-offset of treatment so that potentially large cost-offsets are not used to justify exceedingly high one-time prices.

Valuing new interventions in reasonable alignment with their added benefits for patients and families is a foundation for affordable access that still retains the necessary incentives for meaningful innovation. However, with potentially transformative single-time therapies, traditional methods of cost-effectiveness analysis capture all the estimated lifelong downstream benefits of treatment, including not only health gains but the potential for reducing or eliminating the costs of chronic treatment over many years. Thus, potential cures for expensive chronic conditions can be valued at extremely high one-time prices based largely on these cost offsets. SCD is not as

expensive to care for as some other conditions, notably hemophilia, but consideration over whether full valuation of cost offsets as a part of the gene therapy price are still relevant.

There is nothing wrong with acknowledging the potential for cost offsets in the health system and beyond that may come with transformative therapy. However, assigning all that value in the pricing of treatments raises two fundamental questions. First, should the potential cure for an "expensive" condition be valued exponentially more than a potential cure for a condition that is less expensive, perhaps because it is rapidly fatal and does not accrue high costs over many years? And second, should the pricing of the therapy allocate to manufacturers "all" of the societal value at the incremental cost-effectiveness threshold, particularly when these kinds of treatments are far less likely to ever face generic competition that drives lower pricing?

We believe these two questions make it reasonable for manufacturers, payers, and other policymakers to consider alternatives to full valuation of potential cures based on 100% of cost offsets being assigned to the price of the treatment. There is no normative policy regarding whether a 50%-50% sharing of cost offsets or some other level is most appropriate. Further policy development is needed in this area, but as single-time potentially curative treatments start to come to market, all stakeholders should be aware that different cost-effectiveness scenarios should be considered in arriving at judgments about the ultimate "fair" price for these therapies.

Recommendation 4

Manufacturers should work with payers to create meaningful alternative payment models that can address two key distinguishing features of gene therapies: 1) the significant short-term budget impact; and 2) the considerable uncertainty regarding longer-term safety and benefits.

Attempts to design and implement alternative payment models for expensive one-time treatments are in their infancy in the US and other countries. The significant short-term budget impact of gene therapies can lead small employers to consider excluding all gene therapies from coverage, while larger health systems such as state Medicaid systems may have relatively inflexible budgets that cannot easily manage a surge of high-cost treatments. In addition, valuation of gene therapies must rely on some estimation of their long-term effects, yet substantial uncertainty remains about these effects at the time gene therapies are launched and first priced in the market. Manufacturers should work with payers and other stakeholders to make progress on designing and implementing novel payment mechanisms to address these issues. Alternative payment mechanisms include: 1) expanded use of stop-loss and other reinsurance programs; 2) installment payments linked to tracking of outcomes; 3) warranties linked to tracking of outcomes; 4) subscription payment models paying a set fee for entire populations; and 5) governmental risk pools or formal carve-outs to reduce the actuarial risk for smaller payers.

Clinicians and Clinical Societies

Recommendation 1

Prepare now to update treatment guidelines for patients with SCD immediately upon approval of gene therapies or other new transformative therapies in a form that is easy to interpret and use by clinicians, patients, and payers.

Payers frame their coverage policies using reviews of existing evidence and an understanding of best practice gained from authoritative clinical guidelines. Clinical societies should therefore be poised now to update their practice guidelines for managing patients with SCD the day that any therapies are approved by the FDA.

Patient Organizations

Recommendation 1

Patient organizations have a vital role to play in promoting objective descriptions of the risks and benefits of new therapies to support shared decision-making for every patient. In addition, patient groups have a powerful voice and should apply it to create significant pressure for fair pricing and appropriate insurance coverage across all sectors of the health system.

Advocacy and support groups helping people living with SCD should endeavor to educate patients about the potential risks and benefits of new therapies, particularly those with the potential for substantial harms, and work with other stakeholders to develop and disseminate evidence-based, balanced materials that are accessible to all patients, including those with low health literacy. Patient organizations should work with payers and clinical societies to improve access and to help hold manufacturers accountable for fair pricing.

Researchers/Regulators

Recommendation 1

The FDA, life science companies, and clinical researchers should adopt consistent measures of patient-important outcomes for SCD, including uniform definitions of VOC/VOEs.
Outcomes captured in clinical trials and through registries should reflect all aspects of living with sickle cell disease. Mental health outcomes were highlighted in the policy round table as often overlooked. Regarding VOC/VOEs, it is imperative that the FDA require manufacturer's to utilize uniform definitions in their trials and when possible, the FDA should seek to align eligibility criteria across trials – failure to do so fails the broader scientific and patient communities.

Recommendation 2

Manufacturers and the clinical research community should develop cohort studies and real-world evidence programs to evaluate the longer-term safety and durability of gene therapies.

The small sample sizes of the current trials leave substantial uncertainty about the potential for serious, but rare, longer-term harms such as myelodysplastic events. Additional data are needed to ascertain how lovo-cel, exa-cel and their related conditioning regimens will perform over time and in the real world.

Recommendation 3

Additional clinical trials are needed to compare the safety and efficacy of gene therapies to current standard of care (hematopoietic stem cell therapy [HSCT]).

In the absence of clinical trial data, clinicians, patients, and medical decision-makers (e.g., parents or guardians), and payers are likely to continue to consider HSCT with a sibling-matched donor as the gold standard for eligible patients. However, there is reason to believe that gene therapies may be less risky than traditional HSCT given that it does not impose a risk of graft versus host disease or rejection. Despite these risks, advances in HSCT have lowered the risk of this procedure over time and evidence would be likely be needed for gene therapy to supplant HSCT as standard of care.

References

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2. Kanter J, Walters MC, Krishnamurti L, et al. Biologic and Clinical Efficacy of LentiGlobin for Sickle Cell Disease. *New England Journal of Medicine.* 2021;386(7):617-628.
3. Goshua G, Calhoun C, Ito S, et al. Distributional Cost-Effectiveness of Equity-Enhancing Gene Therapy in Sickle Cell Disease in the United States. *Ann Intern Med.* 2023;176(6):779-787.

Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the July 27, 2023 Public meeting of CTAF.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants	
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*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Appendix Table 2. CTAF Panel Member Participants and COI Disclosures

Participating Members of CTAF*	
Ralph Brindis, MD, MPH, Clinical Professor of Medicine, UCSF*	**Joy Melnikow, MD**, Professor Emeritus, University of California Davis*
Robert Collyar, Patient Advocate, Patient Advocates in Research*	**Elizabeth Murphy, MD, Dphil**, Professor of Medicine, UCSF*
Rena Fox, MD, Professor of Medicine, UCSF*	**Kathryn Phillips, PhD**, Professor, UCSF*
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*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Cecelia Calhoun, MD, MPHS, MBA, Assistant Professor of Medicine, Hematology, Yale University School of Medicine; Medical Director, Sickle Cell Program, Smilow Cancer Hospital	Nothing to disclose.
Jaime Rubin Cahill, MA, MPH, Vice President, HEOR, Vertex Pharmaceuticals	Jaime Rubin Cahill is a full-time employee of Vertex Pharmaceuticals.
Elle Cole, BA, Certified Sickle Cell Medical Advocate, Cleverly Changing, LLC	Nothing to disclose.
Michelle Gourdine, MD, SVP, CVS Health; Chief Medical Officer, CVS Caremark	Dr. Gourdine is an employee of CVS Health. She receives equity interest in excess of $10,000 Agilon Health, had status as a Agilon Health board director, as a Horizon BCBS NJ board director, and at the University of Maryland Medical System.
Jimi Olaghere, Patient Expert	Nothing to disclose.
Patrick McGann, MD, PhD, Director, Lifespan Comprehensive Sickle Cell Center, Rhode Island Hospital and Hasbro Children's Hospital; Associate Professor of Pediatrics and Medicine, Alpert Medical School of Brown University	Dr. McGann received monetary value in excess of $5,000 after serving on a Novartis Safety Advisory Board.
Clark Paramore, MSPH, Head of Value Demonstration, bluebird bio	Clark Paramore is a full-time employee of bluebird bio
John Watkins, PharmD, MPH, BCPS, Residency Program Director, Premera Blue Cross	John Watkins is a full-time employee at Premera Blue Cross.