Request for Proposal: Reimbursement Strategy for Blue Eye Blind Inc.

Company Overview

Company Name	Blue Eye Blind, Inc.
CEO	Burt Macklin
CTO (PI)	April Ludgate
Company website	Blueeyeblindinc.com
Technology Summary	A paired neural implant and augmented reality contact lens system for the treatment of blue eye blindness and its associated damage to the optic nerve
Major market(s)	Blue Eye Blindness Patients (2 million globally); predominantly individuals (of all genders) 50+ years of age
Technology stage	Late-Stage Human Trial
Primary regulatory path	Q-sub (discuss likely path and whether RFD is needed), Pre-IDE, IDE, Q-sub (discuss impending application), PMA/De Novo

Service Request:

Blue Eye Blind Inc. is requesting support to assist in the development of a reimbursement strategy for the market launch of their neural implant and augmented reality contact lens system: BlueViz AR™.

An estimated two million patients, age 50 years or older, suffer from blue eye blindness (BEB) – an optical nerve damage following a fungal infection of *Indigosis Opticans*. The resulting optical nerve damage permanently impacts patient vision, changes quality of life indices, is a contributing risk factor for additional optic nerve injury and contributes to depression and anxiety in affected populations. Blue Eye Blind Inc. has developed a set of paired products, called BlueViz AR, that relay visual information between the retina and occipital lobe, bypassing the optical nerve and restoring sight.

The neural implant technology is very expensive, which may lead to slow adoption by BEB patients. To increase accessibility for all patients, Blue Eye Blind Inc. requires a reimbursement model and strategy that will enable them to profitably commercialize the BlueViz AR™ system. The proposed pricing and payment strategy developed in this program will also be used to support market size analysis for investment presentations.

Deliverables and Reporting Requirements:

Blue Eye Blind Inc. requires a report and action plan to support their reimbursement strategy and planning. This report will determine existing reimbursement codes (if applicable) and or assist with process and information gathering to apply for an additional device category (combination product) for transitional pass-through payment under the Medicare hospital outpatient prospective payment system (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS OPPS). This may include clarifying data elements required to assist with CMS key component determination (which may differ from FDA's primary mode of action determination) [1].

Blue Eye Blind Inc. expects to work with a vendor who is knowledgeable in reimbursement strategies and medical billing for ocular and ophthalmological indications, as well as for Medicare (OPPS) and combination products - products comprised of two or more regulated components [2]. In addition, Blue Eye Blind Inc. requires the vendor to be up to date on new Transitional Coverage for Emerging Technologies (TCET) pathway proposals from CMS for breakthrough devices [3] and maintain current knowledge of the CMS/FDA parallel review program to secure Medicare coverage.

The expected outcomes for the project include recommendations for clinical and economic data and any additional studies required for coverage and coding, revenue and pricing models, and a cost-benefit analysist for the BlueViz AR™ system. If an application for an additional device category for transitional pass-through payment status under the hospital OPPS is determined to be beneficial, and if possible within the established budget, the vendor will develop and submit the required documentation to the appropriate decision making organization(s).

Existing Information Available for Engaged Vendor:

Blue Eye Blind Inc. has identified Argus II – a retinal prosthesis for patients who have lost their vision due to retina pigmentosa, as a similar technology but not a direct competitor. Argus II is marketed under a Humanitarian Device Exemption (HDE) and is not currently covered by commercial or public payers as it's requirement for IRB approval for each use case allows payers to considered it investigational. We anticipate the components of BlueViz ARTM, targeting a much larger effected population will be cleared (510K or de novo) for the lens, and approved via PMA for the implanted element. The selected vendor will conduct discussions with MACS or the CMS NCD office and identify required clinical evidence to support coding and coverage. Consultants will determine if there are additional existing devices, as well as existing coverage, coding, and payment information for any identified competitors or correlates and provide guidelines for Blue Eye Blind to use in the development of clinical evidence and economic data modelling in their upcoming feasibility and pivotal trials.

Vendor Qualifications:

- Describe your experience developing reimbursement strategies for Central Nervous System (CNS) disorders, and in particular, implantable CNS devices
- Describe the depth and scope of your experience securing new codes or submitting device category applications to CMS for combination products.
- Experience requesting (and receiving favorable decisions on) new HCPCS Level I (CPT) Codes from the American Medical Association (AMA) or HCPCS Level II (Section C) Codes from the Center for Medicare & Medicaid Services (CMS) payment codes and submission of these applications to both public and private payors
- Familiarity with clinical trial study design involving CNS disorders
- Successful track record (within the past 5 years) obtaining CMS coverage for innovative medical systems in both the commercial and public payor environments.

References:

1. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/catapp.pdf
2. Combination Product Definition Combination Product Types | FDA
3. https://www.medicaldesignandoutsourcing.com/cms-tcet-transitional-coverage-emerging-technologies-pathway-breakthrough-devices-medicare/