Access to Investigational Medicines Policy

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agenus

1. Purpose

Agenus is committed to responsible, ethical, and transparent consideration of requests for access to its investigational medicines outside of clinical trials. This policy establishes the principles, eligibility requirements, and governance framework for such access.

2. Scope

This policy applies to all Agenus investigational medicines. It covers requests through:

- **Compassionate use in the United States**, subject to FDA requirements.
- **France's AAC (Accès Compassionnel)** framework, as approved by ANSM.
- **Named Patient Programs (paid)** where national regulations allow importation.
- **Cross-border medical care** at accredited medical centers.

Operational details (contacts, forms) are maintained on Agenus' public website.

3. Guiding Principles

Patient safety first: Decisions are based on a rigorous benefit-risk assessment using available clinical and safety data.

- Science-led access: Requests are considered only when sufficient evidence exists to identify an appropriate dose and treatment regimen.
- Integrity of trials: Access must not compromise ongoing or planned pivotal clinical studies.
- Equity & fairness: Requests are evaluated consistently, without discrimination.
- Legal & ethical compliance: All requests must align with local laws, regulations, and oversight requirements.
- Transparency: Policy and material updates are published online with date stamps.

4. Considerations for Compassionate Use Requests (United States)

The following considerations guide Agenus' evaluation of Compassionate Use requests and are consistent with the guiding principles outlined above and follows FDA Expanded Access regulations (21 CFR 312).:

1. Patient has a serious or life-threatening condition with no satisfactory alternatives.
2. Standard treatment options have been exhausted or are contraindicated.
3. Agenus must consider the risk-benefit to be robust and persuasive and reasonably likely to be supported by the FDA.
4. Based on discussions with the FDA, Agenus must have reason to believe the FDA is likely to approve the medicine for use in this population of patients.
5. Patient is ineligible for, or unable to access, an ongoing clinical trial. Geographic limitations to

participation in a clinical trial would generally not meet this criterion.

6. Provision of medicine will not undermine supply or development plans.
7. Request originates from the treating licensed physician (unsolicited by Agenus).
8. Treating institution can comply with informed consent, ethics approval, safety monitoring, and reporting obligations.

All requests are evaluated fairly and without discrimination. Patients with serious comorbidities that may pose heightened safety risks or that remain insufficiently studied may be excluded. Access must comply with applicable national regulations, ethics or IRB approval. Informed consent and agreement to comply with monitoring obligations are required from both the treating institution and the patient (or legal guardian).

5. France's AAC (Accès Compassionnel) Framework (France)

Botensilimab and balstilimab combinations is available by France's National Agency of Medicines and health Products Safety (ANSM) AAC framework; eligibility and hospital-only use are defined by ANSM.

6. Governance & Review Process

- Requests are triaged by Medical Information or by authorized third party provider.
- Agenus may decline or discontinue access if emerging data alter the benefit-risk profile, supply is constrained, or commercial approval occurs.

7. Cost Recovery & Pricing

Agenus may recover certain costs or charge a treatment fee for access to investigational therapies, depending on the access pathway, the applicable legal and regulatory frameworks.

For access programs such as Paid Named Patient Programs and country-specific frameworks like France's AAC, Agenus may charge a company-set fee that includes program administration and other allowable costs, in line with local laws and requirements.

Agenus is committed to setting fair, transparent, and legally compliant pricing across all access programs.

8. Country-Specific Pathways

- **United States:** Access follows FDA Expanded Access regulations (21 CFR 312).
- **France:** BOT/BAL is available under ANSM's AAC framework; eligibility and hospital-only use are defined by ANSM.
- **Paid Named Patient / Cross-Border Programs:** Permitted in select countries; initiated by treating physicians; logistics coordinated with authorized partners.

9. Privacy & Data Protection

Patient data will be processed in accordance with GDPR, HIPAA, and applicable privacy laws.

10. Transparency & Feedback

This policy is posted on the Agenus website. Physicians may raise questions or appeals through designated channels.