Suitability of Managed Access in England to Resolve Uncertainties in the Cost-Effectiveness of Tixagevimab–Cilgavimab (Evusheld) for the Prevention of COVID-19

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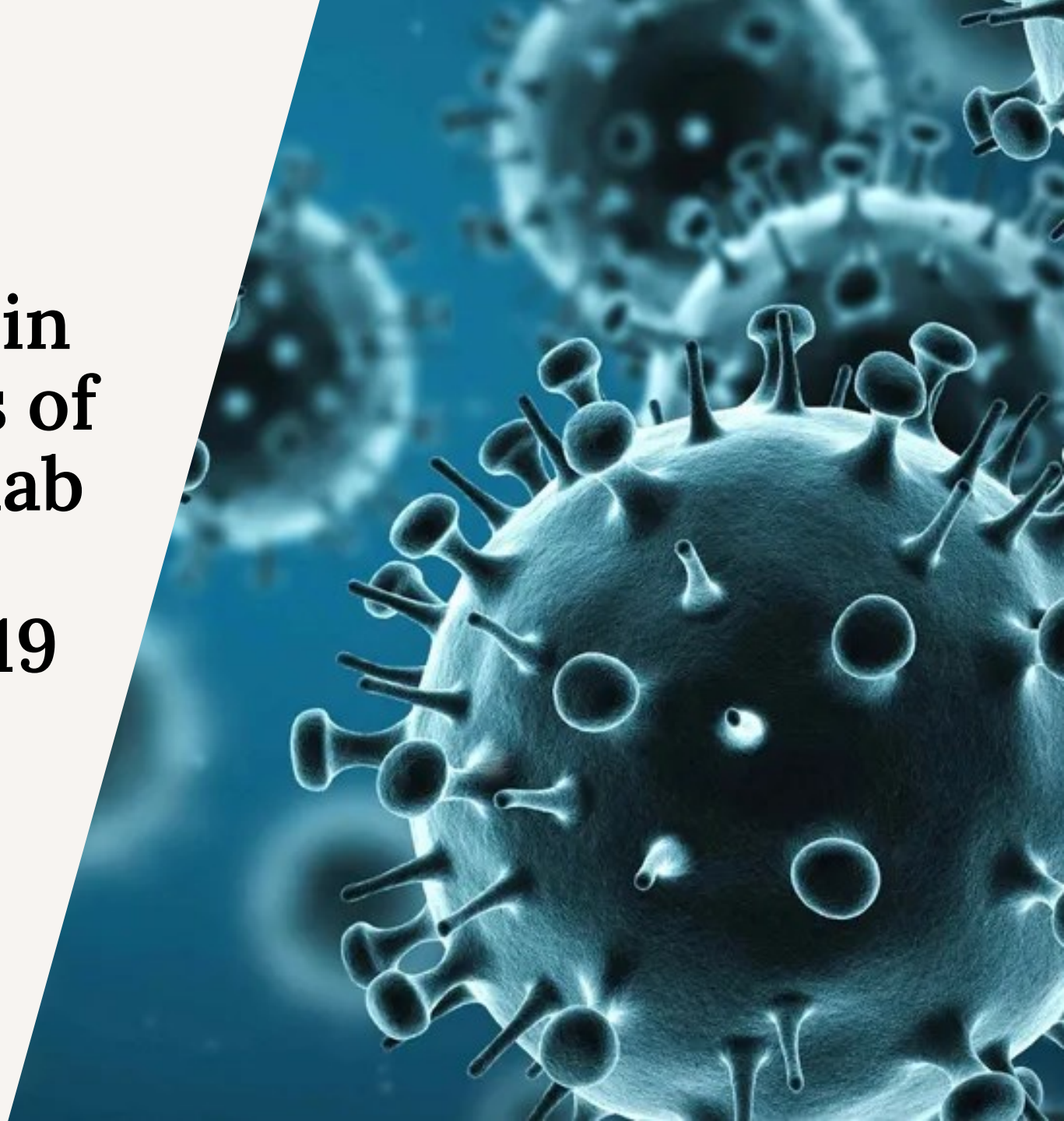

What is ‘managed access’?

Earlier patient access

Promising new drugs

Resolvable clinical uncertainty

Further evidence generation

Plausibly cost effective

- **Managed Access Agreement (MAA) is a time limited arrangement**
- An option for NICE technology appraisals that currently can’t be routinely recommended
- Enables patient access while further data is collected to address the key uncertainties
- Ensure the NHS still pays a cost-effective price, through a commercial access agreement (CAA)

Innovative Medicines Fund: Principles

Equal opportunity for cancer & non-cancer

Targets the most promising medicines with significant remaining resolvable uncertainty

Plausibly cost effective

Priced responsibly during managed access

Shortest time necessary to resolve uncertainties – maximum of 5 years

Entire eligible population can access treatment during managed access

Guidance update by NICE at the end of managed access

All patients can continue treatment in the event of negative re-evaluation

Should never have to close to new entrants

NICE

https://www.england.nhs.uk/publication/the-innovative-medicines-fund-principles/

ID6136 Technology Appraisal for Evusheld for prevention of COVID-19

Population in indication	People who will not benefit from vaccines
NICE Technology Appraisal Committee	To decide whether Evusheld is a cost-effective use of NHS resources
First impressions	Potential IMF candidate. Innovative new medicine with uncertainties that will need further evidence generation
Managed Access Team activity	Feasibility Assessment provided to committee on its suitability for managed access
Appraisal status	Ongoing with rapid review in consultation

Feasibility Assessment

Clinical uncertainties resolvable with data collection

Barriers to managed access

Ongoing or planned data collection

Clinical uncertainties resolvable with data collection

Engagement with NHS England

Feasibility assessment requires managed access proposal from company

NICE

Evusheld: resolving clinical uncertainties with data collection

Key Uncertainties	Potential Solutions
Effectiveness in emerging dominant variants	Ongoing surveillance and reactive guidance updates
Future baseline rates of infection and hospitalisations	Rapid evaluation, including *in vitro* data, of effectiveness of Evusheld on new dominant variants
Common to all infectious diseases	Trigger point for evaluation decided by consultation

Uncertainties currently not considered resolvable within managed access

NICE

Evusheld: ongoing and planned data collection – Real World Evidence

Key Barriers

- No unified data set across primary and secondary care could capture all outcomes of interest
- No longer a widespread testing mechanism for COVID-19 nor genomic testing
- Missing data, lack of national coverage and confounding

Potential Solutions

- Bespoke surveillance process
- Widespread testing and monitoring of patients
- New contracts to share data between sources

Data collection currently not considered suitable for managed access

NICE

Evusheld: barriers to managed access

Key barriers

- RWE data collection would add burden on system and patients
- Time to set up data collection
- Large budget impact

Potential Solutions

- Widespread changes to NHS data architecture
- Patient consent and ethical approval
- Time and money

Barriers considered impractical to resolve within managed access

NICE

Conclusion

- Managed Access oversees time-limited data collection
- Cost-effectiveness of treatments for infectious diseases uncertain
- Current NHS data architecture not suitable for managed access
- Bespoke surveillance process needed for any ongoing evidence generation for Evusheld

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Thank you.