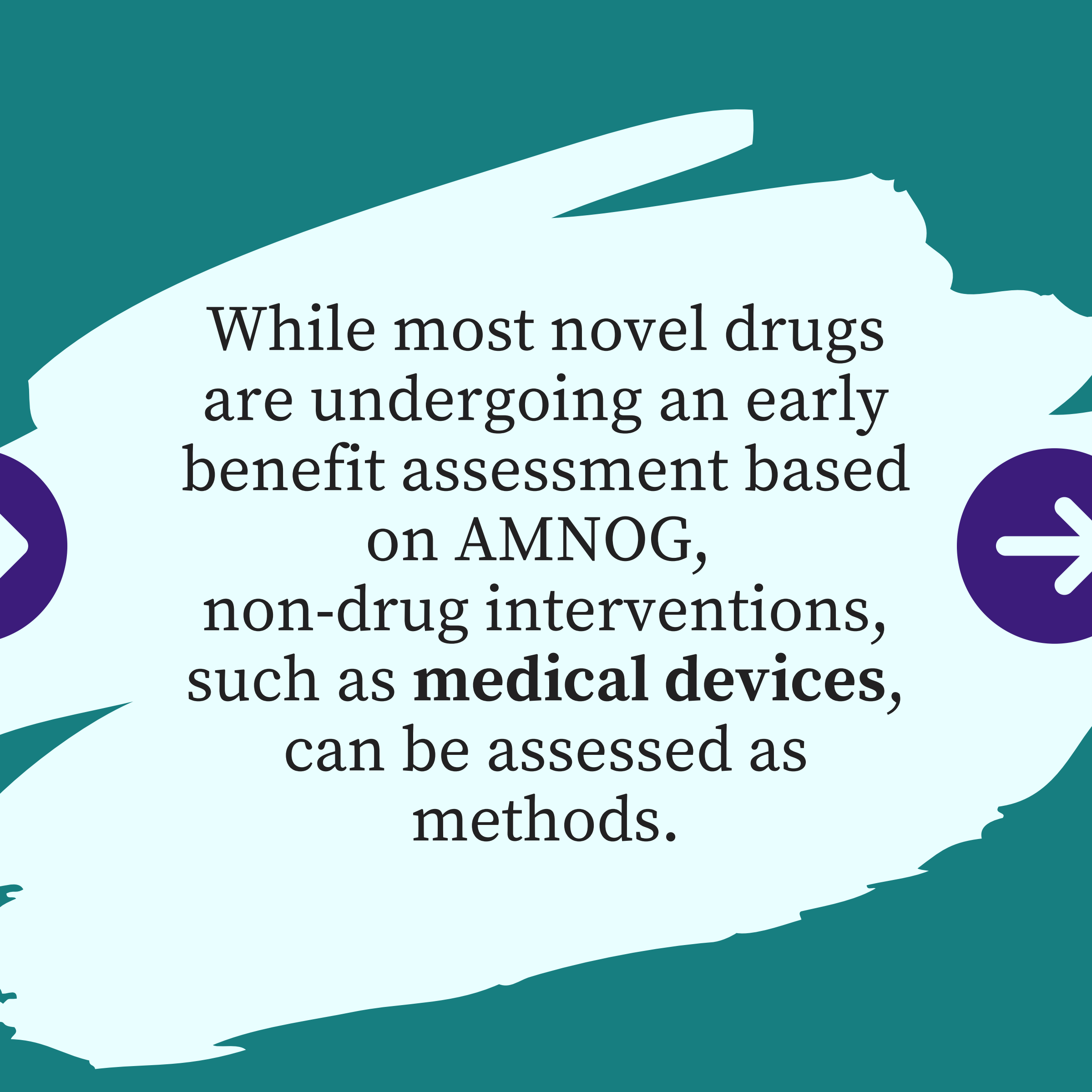




METHOD ASSESSMENTS

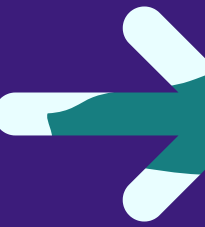


While most novel drugs
are undergoing an early
benefit assessment based
on AMNOC,
non-drug interventions,
such as **medical devices**,
can be assessed as
methods.



1

The G-BA, physicians, hospitals, SHI funds or patients can request the assessment of a new method.



Process of method assessments



Request for assessment

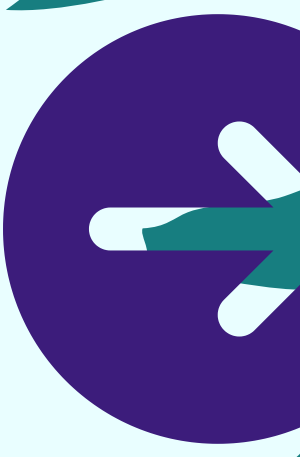


Adapted from G-BA website



2

The G-BA publishes the assessment topic, and contacts clinical experts, manufacturers of devices, and patient groups to offer them a chance for commenting.



Process of method assessments



Request for assessment



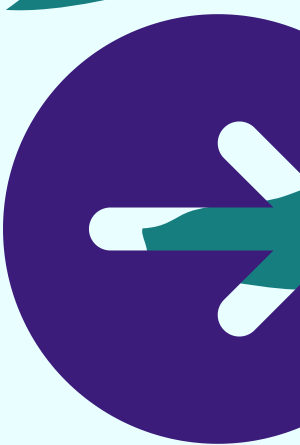
**Publication of assessment
topic for commenting**

Adapted from G-BA website



3

The G-BA or IQWiG assess the benefit and medical need of the method based on all available studies in the relevant indication and patient population.



Process of method assessments



Request for assessment

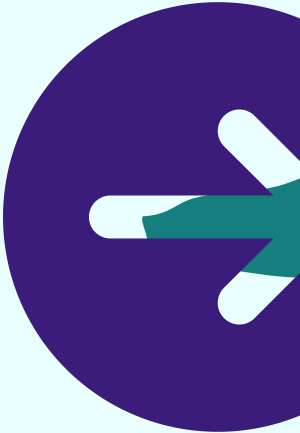
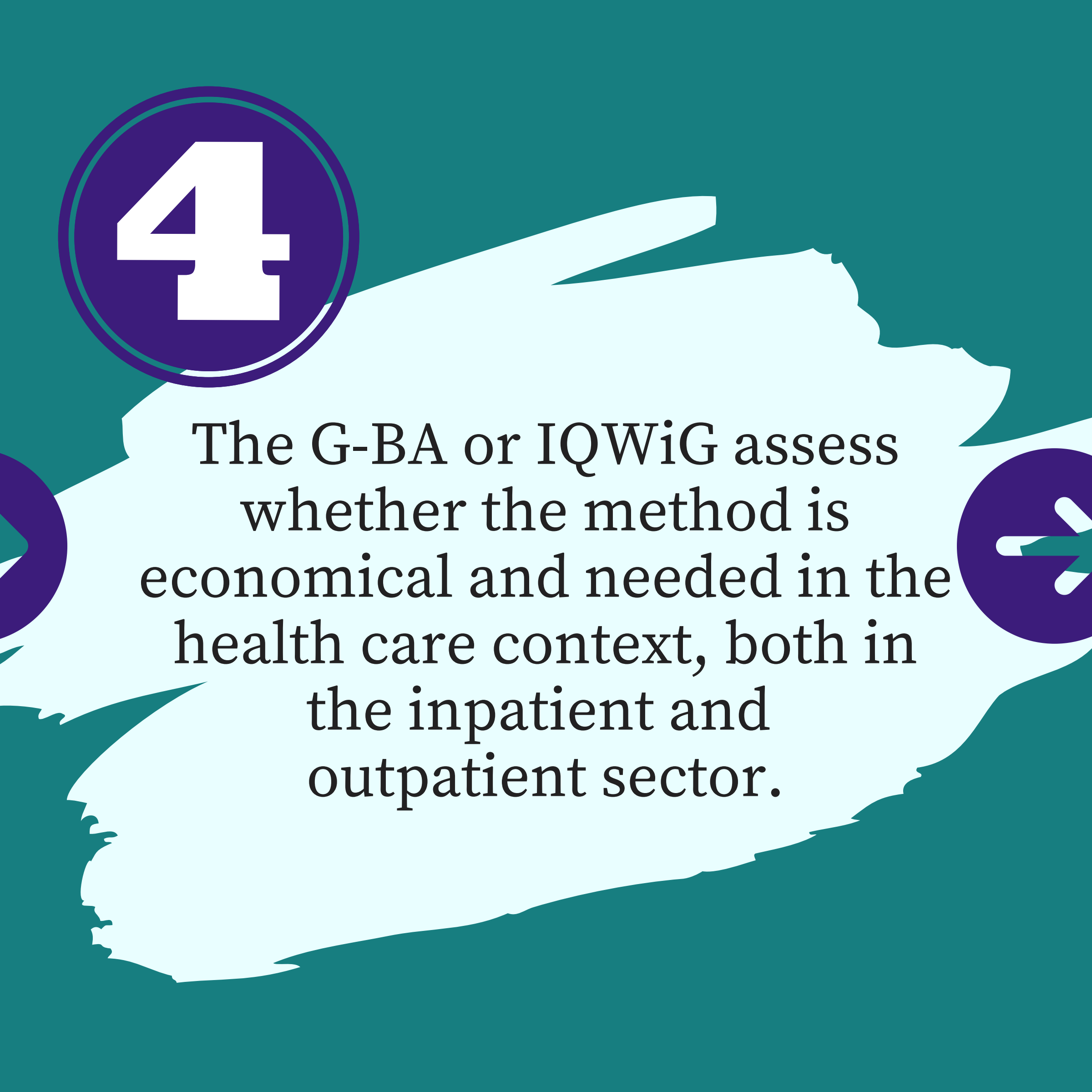


**Publication of assessment
topic for commenting**



**G-BA or IQWiG assesses
benefit and medical need**

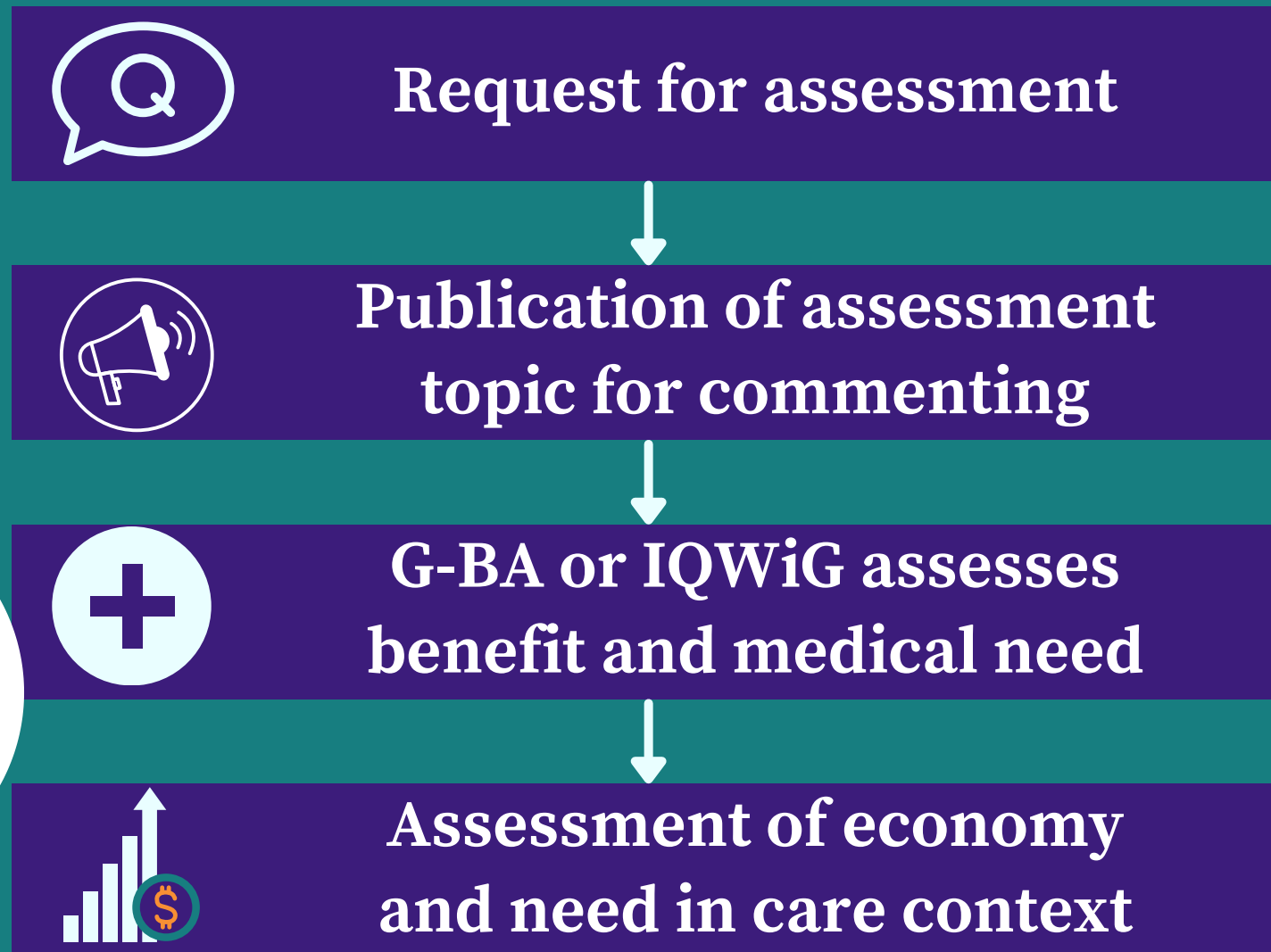
Adapted from G-BA website



4

The G-BA or IQWiG assess whether the method is economical and needed in the health care context, both in the inpatient and outpatient sector.

Process of method assessments

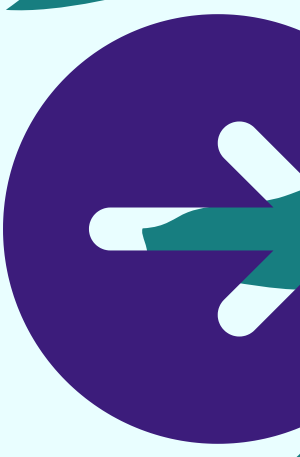


Adapted from G-BA website



5

The draft decision is published, and clinical experts, manufacturers of medical devices, and patient organizations etc. have another chance for commenting.



Process of method assessments

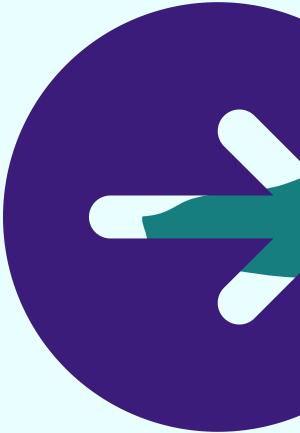


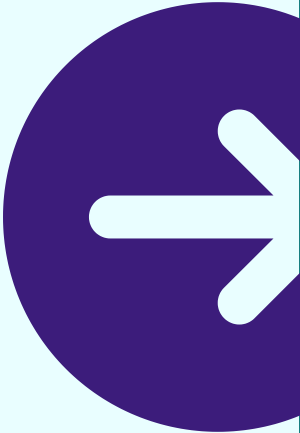
Adapted from G-BA website



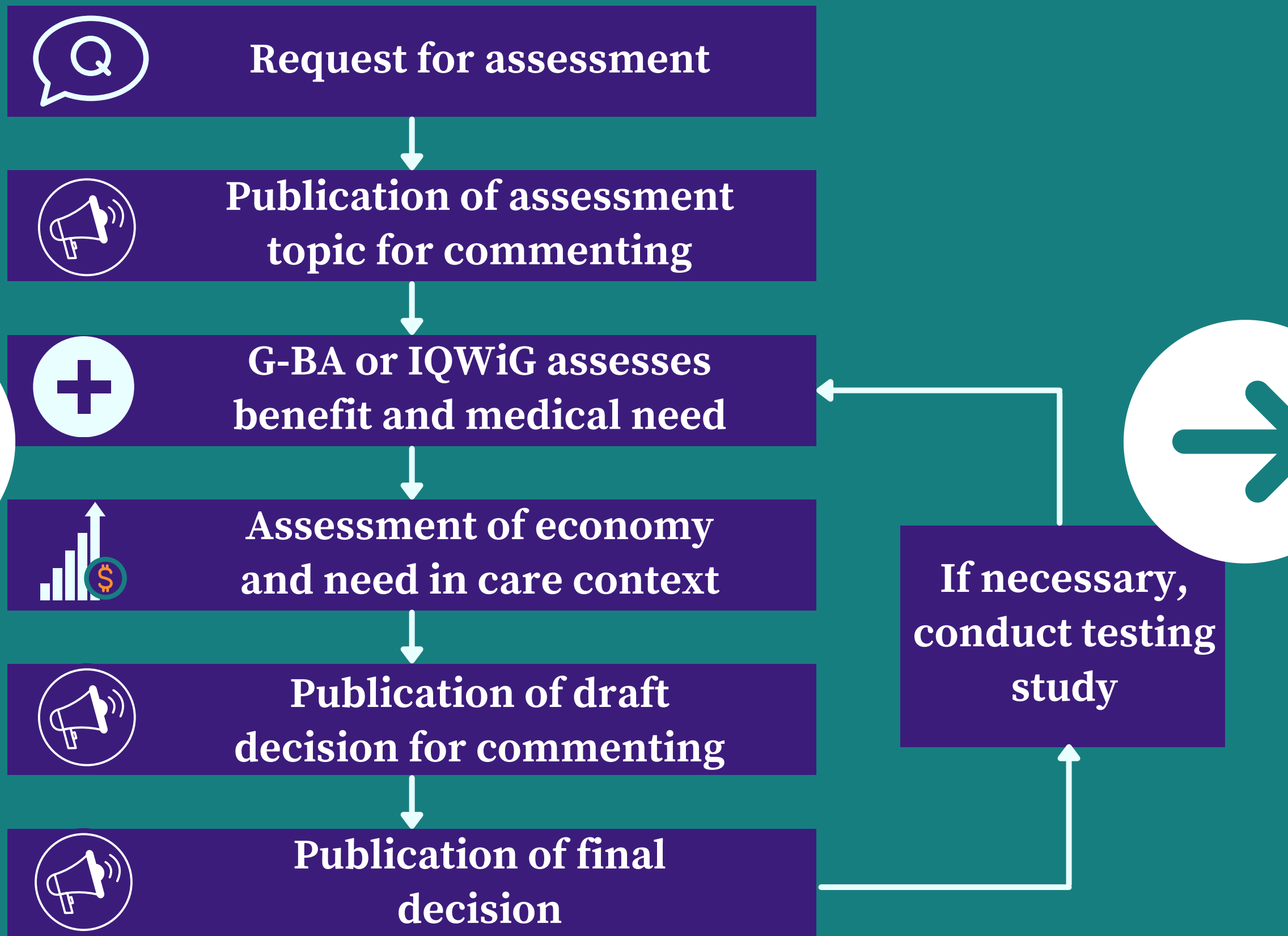
6

Lastly, the final decision is
published.
There are 4 possible
conclusions:



- 
- 
- 1. The method should be reimbursed
 - 2. The method should be excluded
 - 3. The assessment will be suspended for a defined time
 - 4. Testing studies will need to be conducted ●

Process of method assessments



Adapted from G-BA website

As an alternative to the lengthy G-BA method assessment, manufacturers can also directly contract with SHI funds.



Want to find out more?

Get In Touch



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germanmarketaccesssimplified.com

or get my **Free Guide to German HTA system**

A detailed guide to the 10 most commonly asked questions regarding early benefit assessments

