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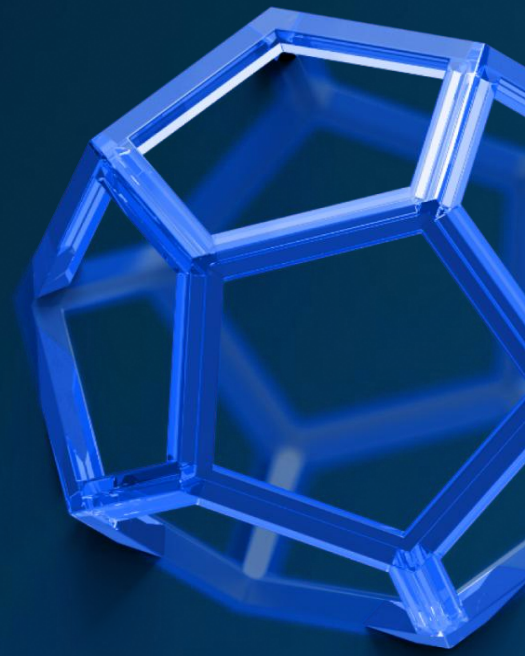
Market Access for Medical Technologies in the Netherlands



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Reimbursement and Acceptance by Payers Represent Two Major Market Access Hurdles in the Netherlands

Reimbursement	Acceptance by payers	Stand-alone HTA
Mechanism to pay for technology or medical procedure	**Independent acceptance by payers or national decision-makers**	**Stand-alone health technology assessment**
○ DRG reimbursement for hospital and ambulatory specialist procedures ○ Add-on reimbursement for some services via supplementary payments (OZPs) ○ Innovative Payment Schemes ○ The creation of a new procedure code for innovative technologies can be connected with the coverage decision process	○ Evidence review via an HTA-based process and a simultaneous decision for coverage in the basic health insurance by the Dutch Healthcare Institute (ZIN)	○ Not relevant in the Netherlands, as HTAs by the Dutch Healthcare Institute (ZIN) are embedded into reimbursement and approval by decision-maker processes

Reimbursement and Coverage Decisions Are Set Nationally, while Insurers Pay for the Services

Policy-makers

Ministry of Health, Welfare and Sport
The ultimate decision-maker about innovative payment schemes and coverage within basic health insurance

Dutch Healthcare Authority (NZa)
Responsible for the development of key policies in the Dutch healthcare system. Supervises core principles of the Health Insurance Act

Dutch Healthcare Institute (ZIN)
Responsible for review of evidence for novel procedures to inform coverage decisions within basic health insurance

Payers

Insurance companies
Responsible for actual reimbursement of health care services

Technical support

Dutch Healthcare Authority (NZa)
Maintains the DRG system and nomenclature of procedure codes

Research

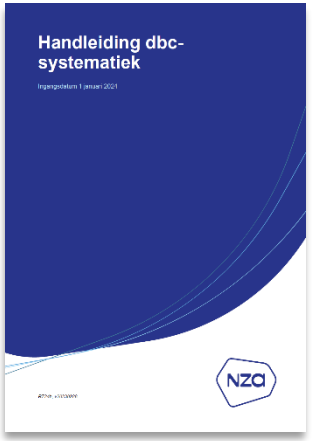
Dutch Organization for Health Research and Development (ZonMw)
Support and financing of research initiatives, including some of the Innovative Payment Schemes

DRG Defines Reimbursement for Specialist Inpatient, Day Case, and Ambulatory Care

- The key payment model for hospital and outpatient medical specialist care is diagnosis-related groups (DBC in Dutch)

- The DRG system is maintained by the Dutch Healthcare Authority (NZa) and is released two times a year
  - The first one is the “A” release, released not later than May 1 (for the next year, starting from January 1)
  - The second one is the “B” release (so-called correction release), released not later than October 1 (for the next year, starting from January 1). Compared to the A release, a correction release contains, in principle, only minor, often technical changes with a low policy impact

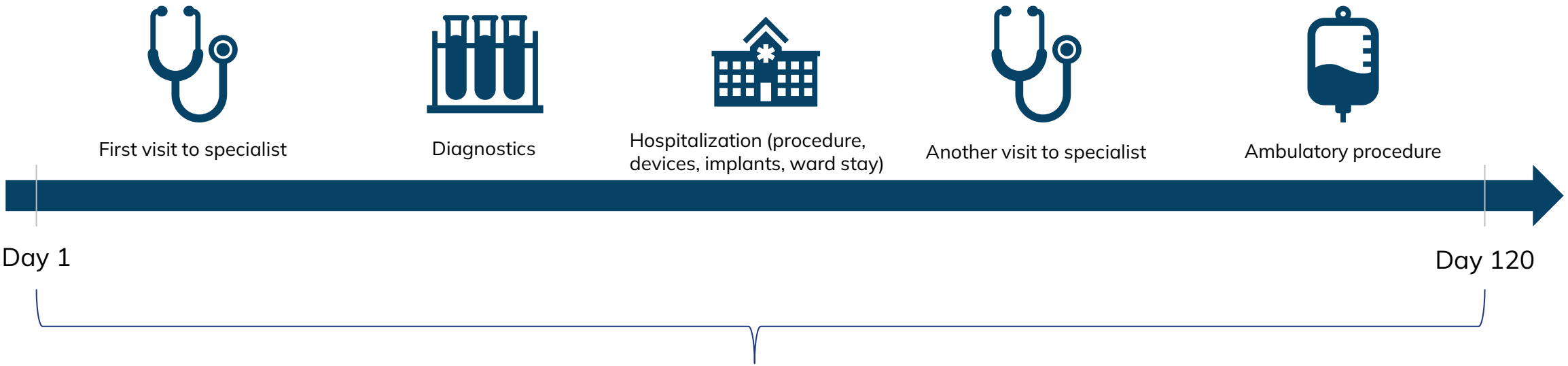
- The maximum period covered by one DRG for one disease is 120 days. All care provided within that period is covered by DRG. However, in the following cases, the period covered by DRG is shorter:
  - 42 days in case of surgery (the list of eligible surgical procedures is defined in the DRG package)
  - 90 days in case of outpatient or day case treatment without surgery



The Dutch DRG System Defines Hospital Reimbursement and Tariffs

- A DRG is determined by the combination of a procedure code (zorgactiviteit) and a diagnosis code
- The Netherlands has its own classifications of procedures and diagnoses
- For the classification of diagnoses, a modified ICD-10 classification is used. Some diagnosis codes can mention procedures as well
- A unique feature of the Dutch DRG system is that the use of diagnoses is limited to certain clinical specialties, i.e., it is impossible to use diagnosis codes with inappropriate clinical specialties. This can create a problem for novel procedures when another specialty should perform them
- Dutch DRGs are divided into two main segments:
  - "Regulated" or A-segment, for which maximum tariffs are set at the national level by the Dutch Healthcare Authority (NZa) (about 30% of DRGs)
  - "Free" or B-segment, where tariffs are negotiated between individual hospitals and health insurers (around 70% of DRGs)
- The Dutch Healthcare Authority (NZa) is responsible for the update of both procedural and diagnosis classifications as a part of the DRG system
- A fraction of specialist services are not reimbursed via DRG. These services are called "Other care products" (OZP), and can be paid individually or as an add-on reimbursement to the DRG tariff (see later)

What does a single DRG cover?



One DRG payment

All medical specialist (inpatient, day case, ambulatory) care under the same specialty and diagnosis provided within a certain period (the maximum period – 120 days; for surgical procedures – 42 days) is covered via the DRG system

VAD Implantation Shows How Procedure, Material, Specialty, and Diagnosis Drive DRG Payment

Procedures performed

Primary procedure code: 033296
Implantation of ventricular assist device (VAD) – long-term support of heart

Material code: 190611
Ventricular Assist Device (VAD) – a device for long-term support of heart

Patient's diagnosis

Medical specialty: 0328 Cardiothoracic surgery

Diagnosis: 2940 Implantation of long-term support of heart

Patient-specific parameters

Discharge method: patient is discharged home
Length of stay: 5 days
Type of setting: Hospital setting

Resulting DRG

DRG 979001129 Implantation of the device for the long-term support heart in a heart condition/lung disease

This DRG belongs to the so-called regulated or A-segment, for which maximum tariffs are determined at the national level by the Dutch Healthcare Authority (NZa)

This amount will cover every aspect of care in the 42 days

The total amount paid for this case is €136,972 in 2024

Services Outside DRGs Can Be Reimbursed via Supplementary Payments (OZPs)

- Specialist services not reimbursed via DRGs are referred to as supplementary payments (overige zorgproducten, OZPs)
- The OZPs can be reimbursed individually (stand-alone payment, in a situation when DRG is not applicable) or in addition to a DRG, and each OZP has a specific procedure code
- The OZPs are determined by the Dutch Healthcare Authority and reported in the DRG system. There are five main categories of OZPs, each of which has subcategories

Supplementary products

- The category includes add-on medicines, clotting factors, add-on intensive care treatment, and other add-on categories
- Supplementary products have maximum tariffs determined at the national level by NZa
- Supplementary products are reimbursed separately or in addition to the DRG

First-line diagnostics (ELD)

- The category includes clinical biochemistry and hematology, imaging diagnostics, microbiological research, pathology, nuclear medicine, etc.
- First-line diagnostics OZPs are paid when requested by GP or other medical specialists as a part of primary care
- OZPs under this category belong to the free segment when the healthcare provider and insurance company negotiate the tariff

Paramedical treatment and research

- The category includes dietetics, occupational therapy, physiotherapy, etc.
- Paramedic OZPs are reimbursed separately from DRGs with a maximum national tariff or free tariffs

Other services

- The category includes dental/maxillofacial surgery procedures, remote consultations for oral diseases, small surgical interventions, prenatal screening, and other miscellaneous procedures
- Other OZPs are reimbursed separately with maximum national or free tariffs

Optional services

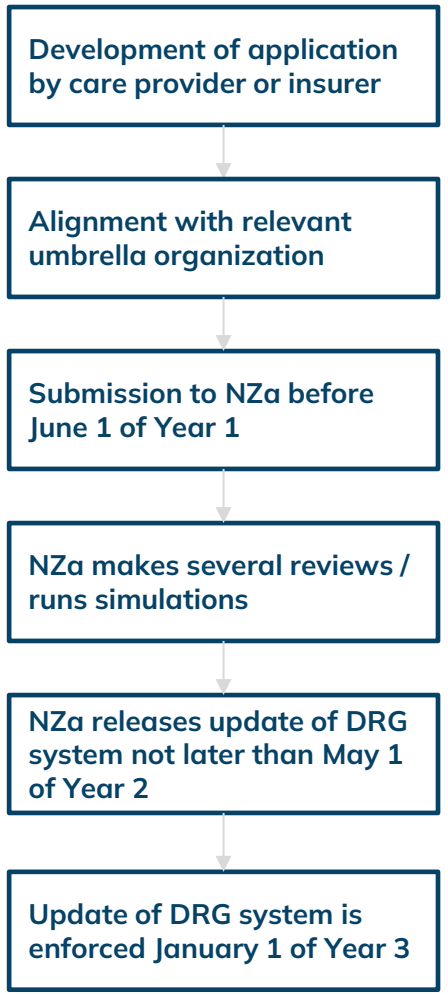
- A way for providers and insurers to innovate on the payment model for care, including the creation of new payment categories or the replacement of existing payment categories
- Applicable to well-established care, which is currently provided as part of the basic health insurance

Other Add-On OZPs Cover Selected High-Cost or Separately Managed Services

- There are several services that belong to the OZP sub-category “Add-on other” (category “Supplementary products”)
- The services are paid in addition to the DRG. Examples of such services are the following:
  - Placement of intrabronchial one-way valve (s) for persistent air leak by therapeutic bronchoscopy (free segment)
  - Telemonitoring (national segment with maximum tariff)
  - ABOi extracorporeal immunoadsorption treatment (national segment with maximum tariff)
  - HLAi extracorporeal immunoadsorption treatment (national segment with maximum tariff)
  - Post-intensive care (national segment with maximum tariff)
  - Additional payment for obstetric high dependency unit (per day) (national segment with maximum tariff)
  - Clinical care in the home situation, including any nursing by the hospital (per day) (national segment with maximum tariff)
  - Fecal microbiota transplantation, per suspension (national segment with maximum tariff)
  - Portable external cardiac defibrillator system (LifeVest) (free segment)
  - Intrabronchial one-way valve for the treatment of persistent air leaks (free segment)
  - LDL (low-density-lipoprotein) apheresis (national segment with maximum tariff)
  - Additional payment connected with chronic ventilation – respiratory rehabilitation (national segment with maximum tariff)
  - Total parenteral nutrition, unprepared, in the home situation, including administration by infusion, aids, and accessories, per day (national segment with maximum tariff)

Dutch DRG Updates Usually Take at Least 1.5 Years

- In order to implement reimbursement changes (i.e., create a new procedure code or update the DRG system), an application must be submitted by a healthcare provider or an insurance company
  - Applications must be supported by the relevant umbrella organization (e.g., Health Insurers Netherlands (ZN), Federation of Medical Specialists (FMS), or Dutch Association of Hospitals (NVZ))
  - The process for creating a new procedure code or implementing changes in the DRG system is the same
- The sole administration of the pathway is the Dutch Healthcare Authority (NZa). It takes 1.5 years to implement changes in the DRG system. Changes are implemented annually (from the 1st of January)
- However, only procedures covered (guaranteed) by basic health insurance can be reimbursed in the Netherlands. In most cases, there is no need for a specific coverage decision
- In case of significantly innovative methods or methods with a high budget impact, a specific positive coverage decision (made by the Minister, based on the HTA by the Dutch Healthcare Institute) is required in order to enable reimbursement
  - In other words, even if technical changes (creation of a new procedure code) are possible, new procedures might not be reimbursed without a coverage decision



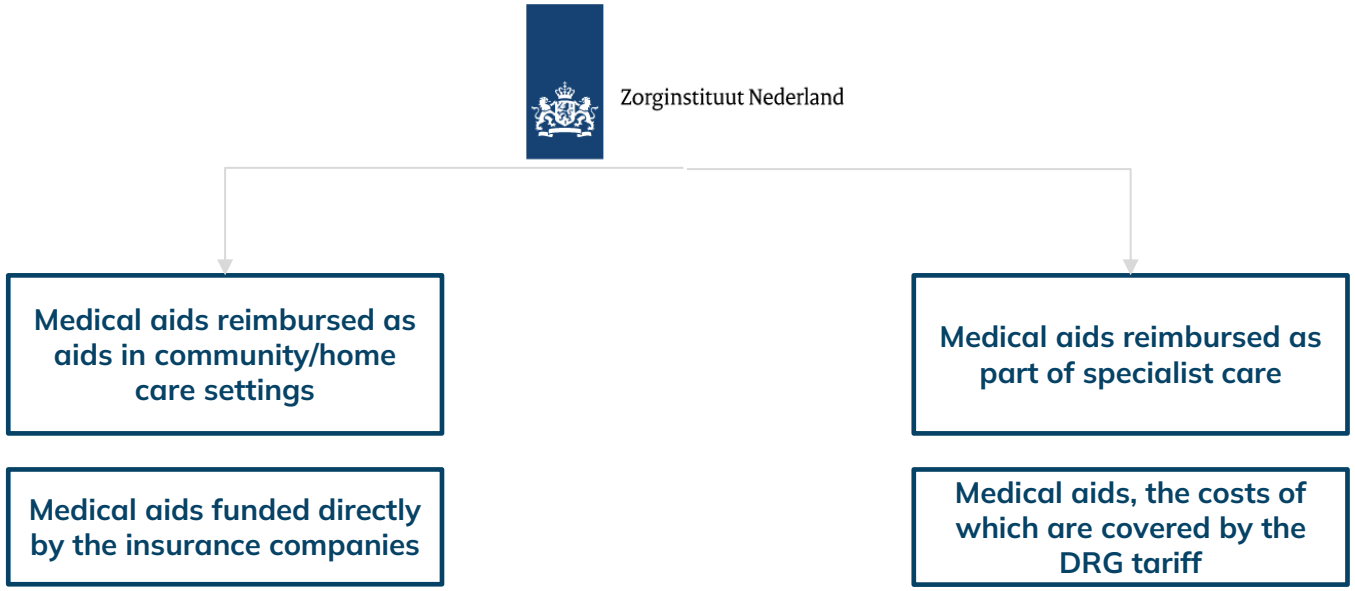
Assessment framework for requests for changes to the DBC system for specialist medical care (2019)

Basic Health Insurance Is the Key Target for Routine Access

Healthcare Insurance Act (ZVW)	Basic health insurance (basic insurance package) covers the standard care, determined at the national level by the Government (based on recommendations by the Dutch Healthcare Institute)
Long-Term Care Act (Wlz)	Coverage of care for people who need 24-hour supervision; commissioned at the national level by the Government
Social Support Act (Wmo)	Provision of support to people with a disability or impediment. The municipality is responsible for its implementation
Youth Act	Provision of support and care for young people and their families. The municipality is responsible for its implementation
Complementary health insurance	Voluntary health insurance covers care that is not included in the basic insurance package. Health insurers determine what is included in it

The Dutch healthcare system is regulated by four system laws. The objective for every novel procedure is to receive explicit coverage within the basic health insurance. If no coverage within basic health insurance is available, it can be covered by individual insurance companies via complementary insurance

General framework for reimbursement of medical aids in the Netherlands



- Medical aids can be reimbursed via two mechanisms in the Netherlands:
  - Funded directly by the insurance companies, if considered medical aids for use in community (home care) settings (medical aids care, *hulpmiddelenzorg*)
  - Covered by the DRG tariff for all care provided within a four-month period, if provided by the healthcare specialist and considered a part of, or a consequence of medical specialist care (*medisch-specialistische zorg / geneeskundige zorg*)
- Some categories of aids, depending on the situation, can be reimbursed via either mechanism
- All relevant accessories to the main aid units are reimbursed via the same payment mechanism

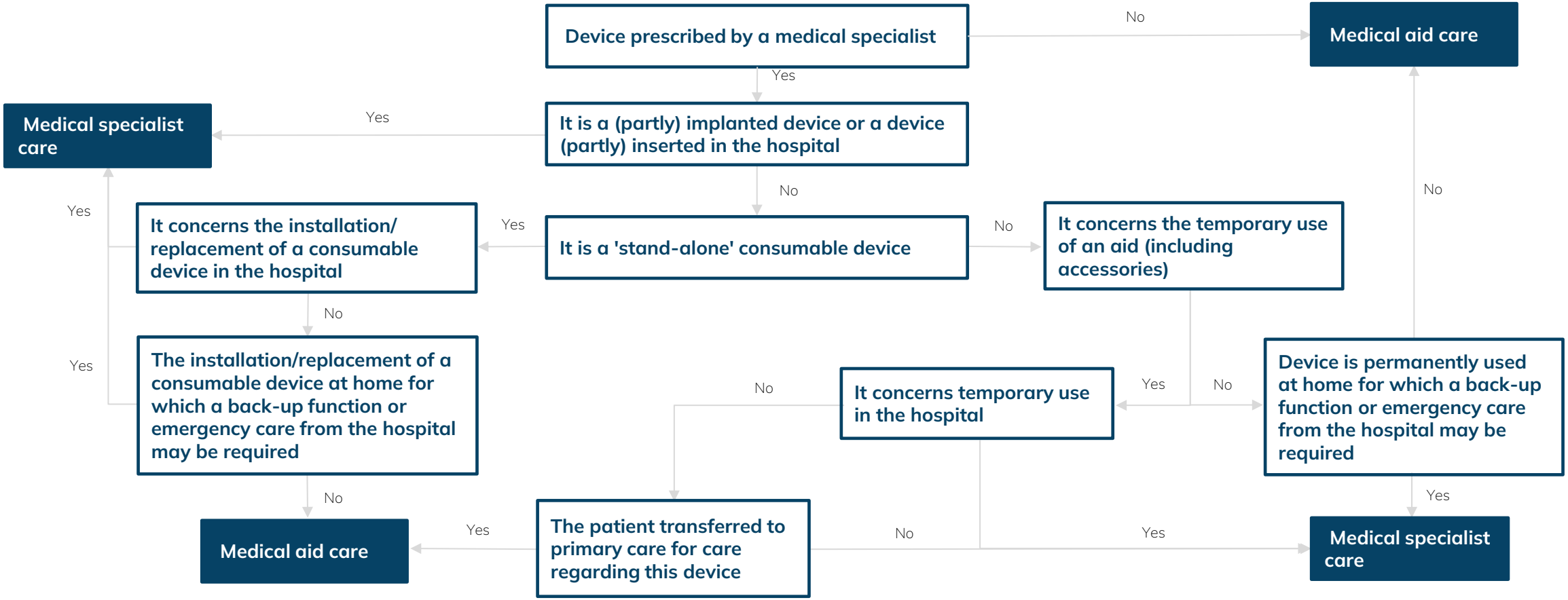
General framework for reimbursement of medical aids in the Netherlands

Type of aids	Medical aids funded directly by the insurance companies	Medical aids covered by the DRG
Part of	Medical aid care (hulpmiddelenzorg)	Medical specialist care (medisch-specialistische zorg / geneeskundige zorg)
Guaranteed by	Healthcare Insurance Act (Zvw)	Healthcare Insurance Act (Zvw)
Coverage of expenses	Individual insurance companies	Hospitals
Co-payment practice	Subject to a compulsory annual deductible Some aids require co-payment	Subject to a compulsory annual deductible No co-payment
Provider of the device	Supplier (as arranged by the insurance company)	Hospitals
Reimbursement mechanism	Insurance companies contract the suppliers	Procurement of aids by hospitals; entire 4-month continuum of care reimbursed by insurance companies to hospitals
Examples of technologies	Insulin pumps, FGM devices, temporary orthopedic footwear, etc.	Infusion pumps for parenteral nutrition at home, home dialysis equipment, etc.

Categories of medical aids according to their reimbursement mechanism

Category 1 (Specialist care)	Category 2 (Medical aid segment)	Category 3	Category 4	Category 5
○ Infusion pumps for parenteral nutrition at home ○ Home dialysis equipment ○ Home monitoring equipment ○ Respiratory equipment ○ Bone growth stimulator ○ PleurX drainage sets ○ Partly implanted hearing aids ○ CPAP ○ UV-B light therapy ○ Vacuum Therapy/VAC Pumps	○ Insulin pumps ○ FGM devices ○ Temporary orthopedic footwear ○ Sleeves ○ Enteral feeding pump	○ Portable external infusion pumps ○ CGM devices ○ Therapeutic elastic stockings ○ Abdominal waistbands ○ Orthoses ○ Corsets	○ This usually concerns consumables or aids that are inserted. For example: ○ Urological catheter ○ IUD ○ Mic-key buttons ○ Tracheal cannulas ○ Voice prostheses ○ PEG probes	○ Probes with accessories, and specific bandages/dressings, only

How is the medical aid reimbursed?



Consumable: a device that is thrown away when a patient 'takes it off' (e.g., bandages, stomas, incontinence materials, test strips, tubes), the patient usually needs several devices per year
Stand-alone: this means that it is not a consumable that comes as an accessory with a main unit
Permanent: permanent does not mean the permanent use of the device during the day, but the fact that the use of or treatment with the device is, in principle, lifelong
Temporary: temporary means that the treatment with the device is finite (depending on the device) within several weeks, months, or years)

Inclusion in the Basic Health Insurance Requires Formal Assessment by the Dutch Healthcare Institute

- In the Netherlands, basic health insurance is determined/guaranteed by the Health Insurance Law (Zorgverzekeringswet, Zvw). The Law describes care in very general terms, so there is a lack of clarity in many situations on what shall be covered
- The Dutch Healthcare Institute (Zorginstituut Nederland) determines care allocation under basic health insurance. The position of the Institute is based on the assessment of clinical and economic evidence to determine conformity of care with the “state of science and practice”
- There are three ways of determining topics for assessment:
  - The institute receives questions about whether care can be covered within basic health insurance from health insurers, healthcare providers, and patients. The institute responds to the requesting party with an answer and interpretation
  - Dutch Healthcare Authority (NZa) can request an assessment during the process of evaluation of the need for the creation of a procedure code, if novel technology/method has a high level of innovativeness or is very expensive
  - In addition to responding to requests from different stakeholders, the Institute regularly reviews the current care package recommendations
- Principles of assessment for inclusion into basic health insurance are determined in the policy documents (Assessment of 'state of science and practice’) from the Dutch Healthcare Institute and joint circular with NZa

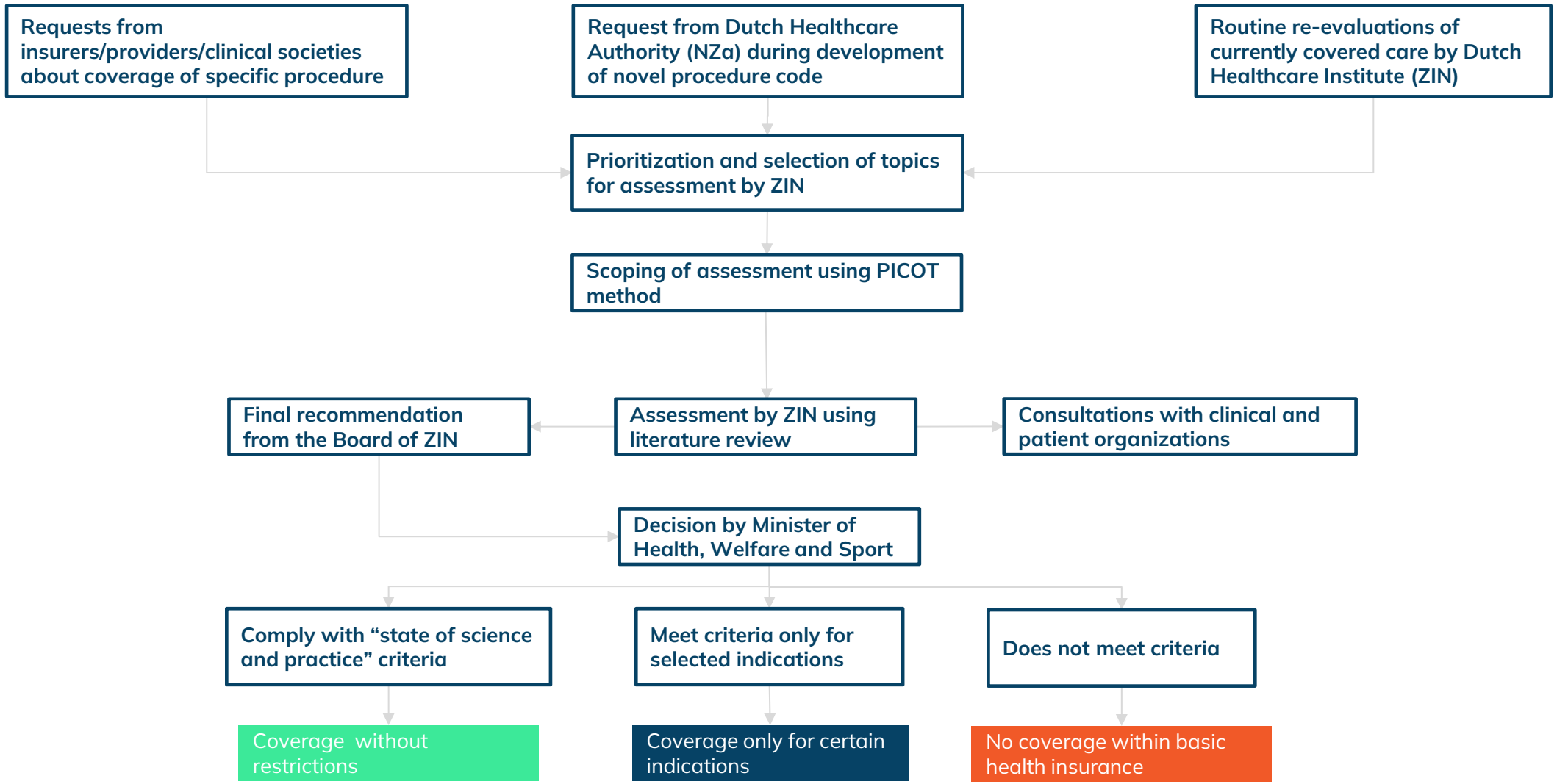
Zorginstituut Nederland

ZIN Coverage Assessment Focuses Primarily on Effectiveness for Final Inclusion Decisions

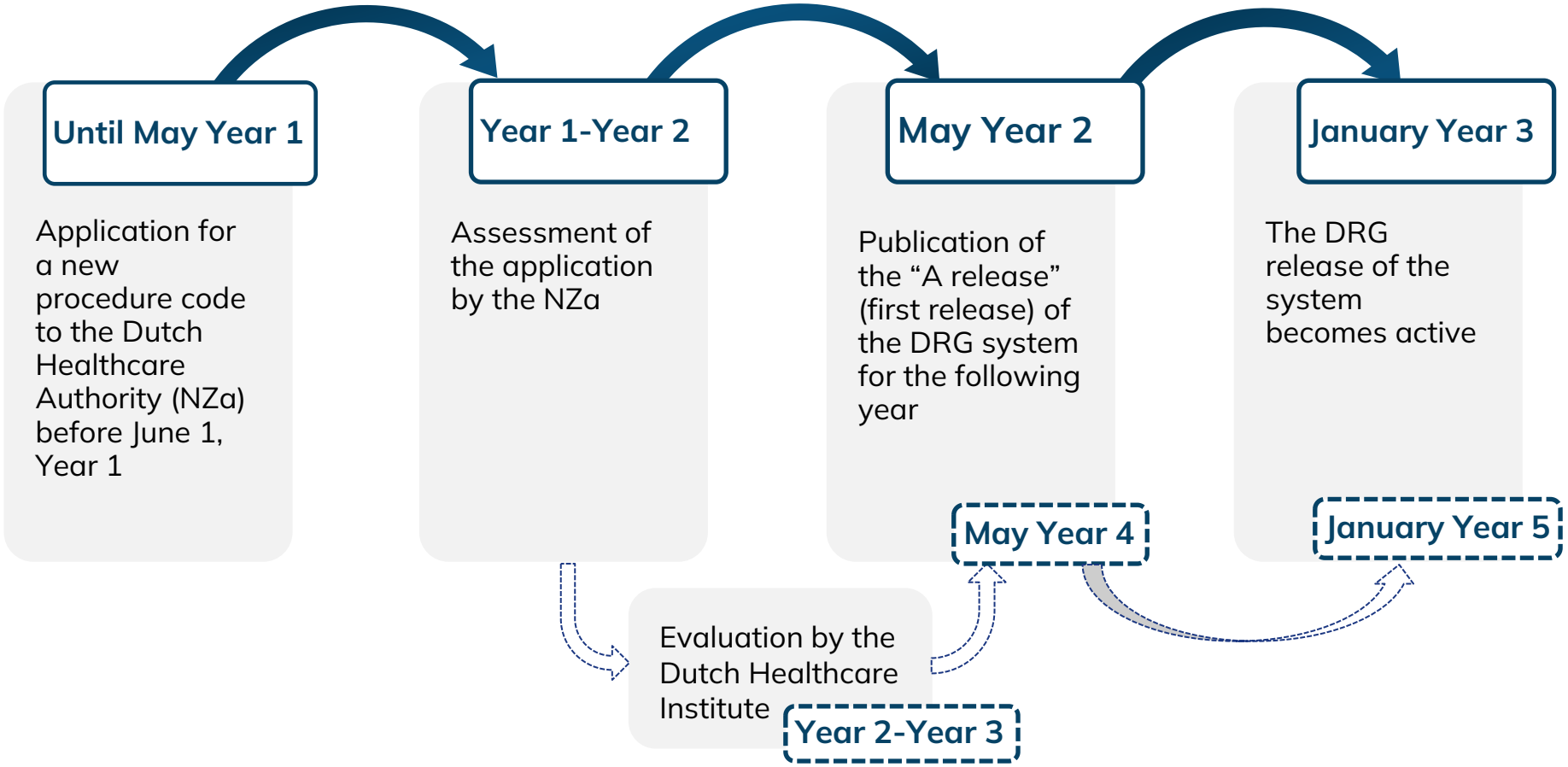
- Procedures are reviewed by the Dutch Healthcare Institute (ZIN) according to criteria of necessity, effectiveness (conformity with “state of science and practice”), cost-effectiveness, and feasibility (later – only in case of review before the implementation of the method). There is a checklist for each criterion with a list of questions
  - Necessity, effectiveness, and cost-effectiveness are used for priority decisions about selecting assessment topics. When actual assessment for inclusion into basic health insurance is performed, it is limited only to the effectiveness domain
  - The total annual cost is presented, but not as part of the assessment, but as an indication of the likely cost in the implementation phase of a new method
- Any review project at the Institute has three phases: scoping, assessment, appraisal of the results of the assessment, and decision. The institute performs consultations on the draft assessment report with different stakeholders, but mainly with Dutch clinical and patient associations. Consultation rarely changes the conclusion, as the position of the Institute has the most weight
- Final recommendations are made by the Board of the Institute to the Minister of Health, Welfare, and Sport. The Minister enables recommendations. In practice, the Minister always follows the recommendation from the Institute
- Decisions of the Institute have a binding effect since publication. Although technical aspects of the decision will be implemented in the next release of the DRG system, the decision has an immediate effect and shall be monitored by insurance companies and healthcare providers
- Care, which is not covered within basic health insurance, is not reimbursed by insurance companies. It might be covered in supplementary health insurance, though. Some procedures are covered by the basic health insurance with restrictions (e.g., by indication)

Zorginstituut Nederland

Coverage Assessment Can Lead to Full, Restricted, or No Basic Insurance Coverage



ZIN Review Can Extend DRG Change Timelines by One to Two Years



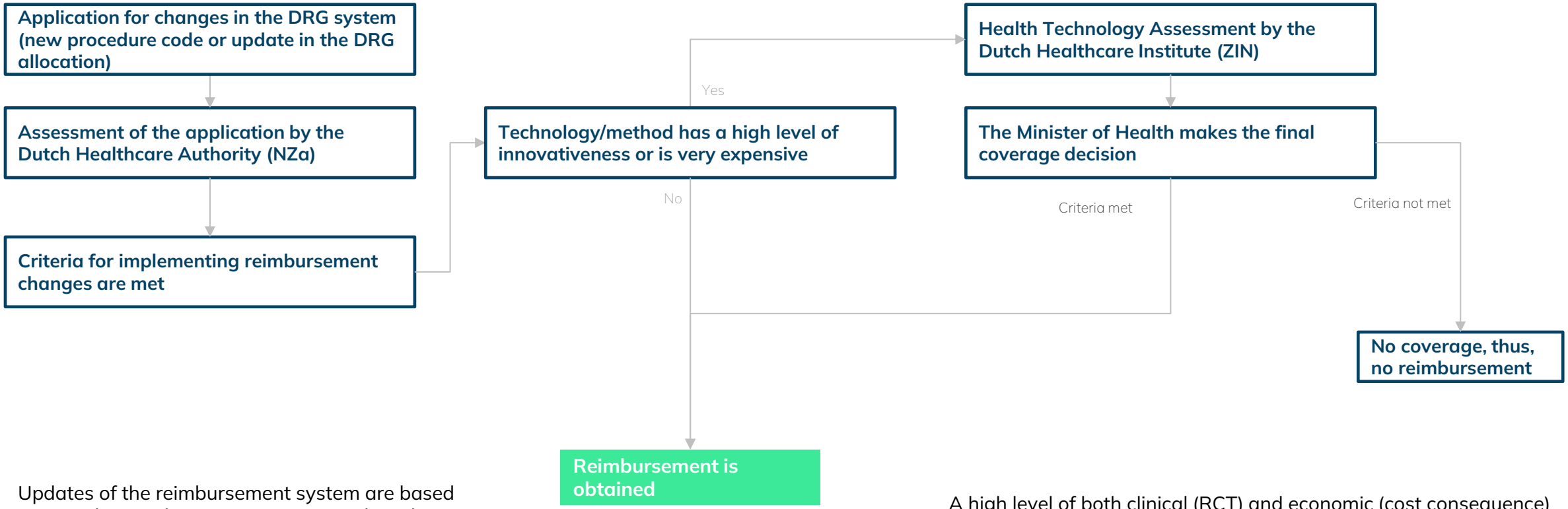
Conclusions

- The integration of a novel procedure into the Dutch DRG system takes at least 1,5 years, in the best-case scenario
- It can take longer if the new procedure/technology triggers a need for a coverage decision from the Dutch Healthcare Institute

Graphical Presentation of the Overall Market Access Pathway in the Netherlands

Reimbursement process

HTA / Coverage decision-making process



Updates of the reimbursement system are based on cost data and quantity estimates. Clinical evidence is not considered the reimbursement process

Reimbursement process lasts around 1.5 years

A high level of both clinical (RCT) and economic (cost consequence) evidence is considered by the ZIN in the evaluation process and coverage decision-making by the Minister

HTA / Coverage decision-making process can prolong the reimbursement process for another 1-2 years

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