NAPPI CODE REGISTRATION AND REVIEW PROCESS 2023

DISCOVERY HEALTH

2023

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Industry overview

A National Pharmaceutical Product Interference (NAPPI) code is a unique product identifier for price adjudication in an electronic environment. The NAPPI is the only accepted code for product identification by all healthcare funders in South Africa.

MediKredit Integrated Healthcare Solutions owns NAPPI codes in South Africa and is the only organisation that can assign NAPPI codes. MediKredit created a stipulation allowing healthcare funders to help govern NAPPI codes by implementing the NAPPI Advisory Board (NAB). This is a non-profit organisation representing hospitals, medical schemes, medical scheme administrators, and medical and dental associations.

MediKredit is responsible for managing and maintaining the NAPPI file depending on the governing authority of the NAPPI Advisory Board (NAB).

Terms and definitions

Term	Definition
List price, including VAT	This is the price submitted to MediKredit when applying for a NAPPI code. The list price is the price at which the supplier sells the product to their customers before any discount.
Max nett acquisition price	This is also known as the max net acquisition price (NAP) or best acquisition price (BAC). It is the price at which the product is supplied to hospital groups after discounts are applied.
Global Medical Device Nomenclature (GMDN)	These generic names are used to identify all medical devices managed by the GMDN agency. The main purpose of GMDN is to give healthcare authorities, healthcare regulators, healthcare providers and manufacturers a naming system that can be used to exchange medical device information and support patient safety. Visit the GMDN Agency online at www.gmdnagency.org.
Catalogue number	Used by manufacturers and suppliers as unique product and pack size identifiers in their price catalogues and invoicing to their customers.
Approved product list (APL) letter	The APL is the reimbursement letter communicated by the Surgical Risk team after their benchmark review process.
Quality accreditation	Products that have undergone an accreditation process and subsequently been assigned quality assurance, such as CE, FDA or ISO.
Comparator products	Products produced by different manufacturers but that have similarities in core function and use, device material and attribute assortment. They do not have to be the same to be a comparator
South African Health Products Regulatory Authority (SAHPRA)	South African Health Products Regulatory Authority (SAHPRA) oversees the regulation of health products, including: · Medicines · Medical devices · In-vitro diagnostic tests and devices · Radiation emitting products · Devices used in the healthcare industry SAHPRA replaced the Medicine Control Council (MCC) as well as the Directorate of Radiation Control (DRC).

NAPPI codes

A supplier must have a NAPPI code so that the private healthcare sector can reimburse the products electronically. MediKredit is the custodian of NAPPI codes and manages its own Product and Price File. Suppliers or manufacturers of surgical consumables and devices, as well as ethical medication must apply to MediKredit to get a NAPPI code for their products. This service comes at a fee. Suppliers or manufacturers must give product information and the list price inclusive of VAT during the application process.

Discovery Health has its own internal benefit management system for the Discovery Health Medical Scheme and the other medical schemes it administers. We are the Product and Price File custodians of the Pharmacy Benefit Management system. This team manages the product listings and the prices of all products on the system. This aligns with our business strategy of giving the medical schemes we administer a comprehensive suite of managed care services.

Discovery Health's NAPPI registration process

Once MediKredit assigns a NAPPI code to a new product, the code is included in the public domain file. You can view the new public domain file on the MediKredit website daily at www.medikredit.co.za.

The price file team are notified when new NAPPI codes are added to the public domain file. Our Price and Product File Team then contacts the manufacturer or supplier and asks for the following information on the price file template:

- Product information e.g. active ingredients
- GMDN code for surgical devices and consumables
- List price, including VAT, for products where prices are not regulated by SAHPRA
- Price effective date
- Max nett acquisition price
- Quality accreditation
- Comparator catalogue number or comparator NAPPI codes

Once this information is received, the NAPPI code is published on the Price and Product File. This means that the NAPPI code can be claimed electronically. The NAPPI then proceeds to be reviewed by the Surgical Risk Team (surgical items) or the Drug Risk Team (ethical items).

It is important to be aware that although a NAPPI code is enabled for electronic processing and listed on the Price and Product File, it does not automatically guarantee reimbursement.

Discovery Health should be given timeous notice of a new product launch. This will ensure that the company's decision to fund or not to fund occurs prior to the introduction of the product into the market.

NAPPI review process for surgical products

The Surgical Risk team follows an additional review process and once complete a letter confirming the reimbursement outcome is sent to the supplier. If the product is approved, it will be listed on the Approved Product List (APL). The review process takes approximately ten working days. To avoid administration delays please ensure that the price file template is completed in full.

These are the review processes for the various product categories:

1) ***Auto approval:***
   - Applies to "Me-too" technologies where the clinical outcomes and the price is the same or lower than a comparator.
   - Should the product fall within an existing category of devices and within the reference price band of the category, it will be automatically approved
   - A decision letter will be sent to the supplier from smart@discovery.co.za

2) ***Price negotiation for "Me-too" technology where the price is higher than the comparator:***
   - Should the product be found to fall within an existing category of devices but is at a premium price compared to all devices within the category, it will be "pended." Further information on the product is required to justify the premium price. A request will then be sent to the supplier to complete a product information notification (PIN) form with the additional information.
   - Should a dispute remain regarding the premium price, the supplier will need to follow the Health Technology Assessment (HTA) process.

3) ***Non - Chargeable or Scheme Exclusions:***
   Should the product be found to fall within these categories the supplier will receive a letter indicating the decline and reason.

4) ***New Technologies:***
   - A new technology is classified as:
     - an existing product with a new indication/use or function.
     - a product with an enhancement/improvement on an existing product with a premium price request
     - a product with no existing comparator on the market
     - An ethical product/medicine, any product with a new active ingredient/molecules
   - The HTA process will need to be followed for new technologies.
   - The supplier must provide published clinical evidence to demonstrate the improved clinical outcomes to justify the price. In addition, the outcomes should be measurable in local claims data.

The full APL for a specific manufacturer can be requested, by that manufacturer. This will confirm the reimbursement and listing of all their NAPPI codes. On a monthly basis the APL is communicated to all hospital groups.

Note: smart @discovery.co.za is a no-reply email address. For queries on the review process or reimbursement letters please contact isem@discovery.co.za.

Health Technology Assessment (HTA Process)

Discovery Health is committed to providing our members with funding for the best quality health care available in South Africa, while ensuring that their cover remains affordable and sustainable in the long term.

The Centre for Clinical Excellence (CCE) will review a new technology (medicine, medical and surgical procedures and devices, diagnostics and pathology tests) using a rigorous, evidence-based decision-making process consisting of a clinical and financial filter.

The clinical filter uses published evidence-based literature, the opinion of local and international key opinion leaders and current treatment guidelines to ensure that the health technology is safe and clinically effective. The financial filter assesses the health economics and budget impact of the new technology to ensure it is cost-effective and affordable.

Discovery Health rules for funding of new technology

1. To determine whether Discovery Health will fund a new technology it must be assessed according to our clinical and economic review process which includes submission of the following information:
   - Clinical evidence-based data to prove that the technology is safe and effective
   - Clinical indications of the proposed treatment
   - Details of costs associated with the technology as well as costs of comparative technologies, where available
   - Any health economic data to support the cost-effectiveness of the new technology.

2. The required information should be included in the completed Discovery Health Technology Evaluation Document and submitted by the manufacturer to the Health Technology Assessment Unit or to the Surgical Risk Unit.

3. Discovery Health reserves the right to decline funding for a new technology until such time as it has been assessed by the above process and a decision has been made regarding payment thereof.

4. It is incumbent upon the manufacturer of the technology to inform Discovery Health of the future introduction of such treatment to the health care market for it to be subject to the clinical and economic review process.

5. The HTA review process takes a minimum of 6 months to complete.

Approval for new equipment

Equipment used in hospitals and/or in the health care practitioners (HCP) practice may need a billing code.

- Investigate if a billing code exists that applies to the new technology/equipment
- If owned and used by Health Care Professional (HCP), the supplier needs to contact SAMA or liaise directly with the HCP with regards to the appropriate billing codes.
- If owned and used by a hospital, the supplier needs to contact the relevant private hospital to introduce the equipment and discuss the appropriate tariff codes.
- If a new code is needed, this should be initiated by the respective hospital group e.g., HCP or Hospital. Suppliers cannot apply for a new code, it needs to be done through one of the above communication channels.
- If the equipment is classified as a new technology this will likely undergo the relevant HTA process.

Approval for digital technologies

Digital health products will include categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

When Discovery considers a digital device, the surgical risk team will undertake a process of due diligence on the technology itself and the vendor/manufacturer. The reimbursement and incorporation of the product into benefits will be dependent on the process outlined below. The company must have a SAHPRA licence.

The main areas considered are:

- **Clinical evidence** – The product must be assessed according to our clinical and economic review process. The product needs to undergo the HTA evaluation process. The HTA process is defined above.
  Should the device pass the clinical and financial assessment, the devices selected for integration will be reviewed on a case-by-case basis depending on the underlying business needs. Suppliers will receive a letter indicating the reimbursement outcome. The basket of funding will be outlined in the letter
  .
- **Reliability and national support structure** – the team will consider the retail footprint of the device vendor/manufacturer to ensure access to the members and providers.

- **Functionality**: The minimum requirements and clinical outcomes of the device must be clearly stipulated including the ease of technical integration. The integration with Discovery Health's clinical data repository allows members to share their data with their doctors through a seamless digital process to monitor clinical outcomes.

- **Data protection**: The vendor/manufacturer must be able to ensure that the member's data will remain secure. Devices and platforms will be subject to a data security and privacy evaluation.

NAPPI review process for ethical products

Ethical products are reimbursed based on the benefit the product is being claimed from. There are two main categories:

- Funding from the Medical Savings Account (MSA)
  When a member does not have an authorization for an ethical product from a risk benefit (Chronic Illness, HIV, Oncology or PMB), the funding decision will come from their available MSA or members own pocket (MOP). Reimbursement will depend on the type of product and whether it is eligible for MSA funding or a General Scheme Exclusion. If the product is eligible, it will depend on the member's plan type and whether they still have funds available in their MSA. Plans without MSA do not have this option available and claims will be for MOP.

- Funding from Risk Benefits (the scheme)
  Risk funding depends on whether the member has an authorization for a product from a risk benefit. Once an authorization is granted the level of reimbursement will depend on the type of product.

Annual Inflationary Price Increase Process for Surgicals

The manufacturer needs to supply written notification to Discovery Health of the intent to submit a price change. The price file team do not automatically receive price updates from MediKredit.

There shall be no automatic annual adjustment of prices. Prices shall not be adjusted by an amount exceeding the Consumer Price Index (CPI) or the agreed appropriate scheme tariff schedule for the year. The price increase template should be completed and sent to the Surgical Risk team for review. You will receive confirmation that your request has been received and you will receive a written acceptance of this adjustment if it meets criteria.

Price changes for ethicals

- Discovery Health updates the single exit price (SEP) ethicals using the Department of Health (DOH) files. These are received directly from the DOH.
- For other ethical products, the MediKredit price is used. This must be submitted by the manufacturer directly to the price file team at Price_and_Product_File@discovery.co.za. Price changes are not received from MediKredit.

Our confidentiality policy

The information a manufacturer supplies is dealt with the strictest confidence. It is used for internal product classification, pricing and reimbursement purposes only.

Contact the team

Price and Product File - PRICE_AND_PRODUCT_FILE@discovery.co.za

- New product information and pricing
- Updated product information and pricing
- Change in contact details
- Notification of company name changes, mergers, etc.

Surgical drug risk – ISEM@discovery.co.za

- APL
- Approval for Digital technologies
- Annual price adjustments
- Approval for new equipment
- HTA process

Drug Risk - drm_team@discovery.co.za

- Formulary considerations (only SAHPRA registered schedule 3-6 products)

Centre of Clinical Excellence - cpuwatchlist@discovery.co.za

- New technology review