Introduction

The High Cost Device List (HCDL) is an important component of the Tariff with regard to technology dependent procedures. We highlight two interlinked concerns as regards this list:

- Lack of structure and transparency within the functioning of the list
- The process by which centralised procurement of high cost devices is being implemented.

ABHI and its members are committed to the continued support of the heath system through delivery of innovative products. Increasingly industry is also delivering the service support required to improve access to interventions and manage patients in a cost-effective manner.

ABHI endorses efforts to improve transparency in pricing. The cost of product or service should be accurately reflected in reimbursement mechanism to ensure that providers are reimbursed appropriately and avoid any requirement for services to cross subsidise.

Structure and Transparency:

There is opportunity to improve the functioning of the HCDL by:

- Clarification of the aims and purposes of the High Cost Device list as regards supporting innovation adoption
- Increased transparency on decision making. Criteria for acceptance and removal from the list should be included in the national tariff methodology consultation
- Creating a feedback mechanism to stakeholders on rationale for inclusion/exclusion decisions
- Increasing clarity of products captured within the generic categories, based on input from providers, commissioners and industry partners.

Centralised Procurement

The above issues regarding specificity and clarity of criteria and process are now more acute given the HCDL will form the basis for a centralised procurement exercise.

This was originally outlined by NHS England in its Commissioning Intentions for 2016-17 and is referenced in the 2016/17 National Tariff Payment System at para 294; Rule 7, Local pricing rules: Rules for high-cost drugs and listed procedures.

This clause references “a requirement to use a supplier or intermediary, or via a framework, specified by the commissioner.” It has since been clarified that the term “supplier” does not refer to a device manufacturer. We would reiterate that diversity of supply, competition and hence clinical choice is a fundamental mechanism to support patient access and outcomes.

We understand the intent of centralised procurement is to save £60m over two years on the specified devices by reducing the variation in acquisition cost and in “pass through” costs.

Price variation can arise through several different mechanisms, including:

- Inconsistent tender process
- Varying product and system offerings between companies
- Varying provider requirements for products and services
- Limitations of tariff system encourage package specifications
- Incentives and on cost of the tendering party
- Business models which reward commitment levels and volume and/or link capital and consumable and capital elements.

We recommend the following principles be incorporated into the procurement activity:

1. Transparency

Manufacturers and providers need clarity prior to transfer to the proposed new arrangements. The tariff document references "High Cost Devices" whereas the Standard Contract clause only applies to Specialised Services, the product ranges within scope need clear definition.

2. Clarity

The current high cost device list is sometimes ambiguous about which products are within a category heading. NHS England should not introduce national procurement until the scope, process and timescales have been clarified to trusts, commissioners and the industry.

3. Maintaining clinical choice

We welcome the statement by NHS England that **"all products currently available will continue to be available to clinicians".** Medical devices vary in design and specification enabling a wide range of options to allow for differences in clinical presentation, patient need and clinician preference. We believe that any procurement route should focus on achieving best overall value whilst maintaining clinical choice.

Clinical input should be sought from the Professional Societies, Associations and Patient Groups that have an interest in the procedures in which excluded devices are used.

4. Investment in value and outcomes

We welcome the NHS England statement that "savings which will be reinvested into other specialist services and treatments". However, consideration should also be given, through a rigorous and transparent prioritisation process, to levels of penetration within the areas impacted by this project. Any efficiencies realised through procurement should be reinvested into wider and equitable access for patients. Inequitable access should be eliminated in order to achieve "Right Care". Appropriate target implant/usage rates should be set in consultation with clinical societies and monitored by establishing a registry to track usage and outcomes. This will enable a robust measure of value and provide a feedback loop to commissioners and users. This in line with the principles of "Right Care".

5. Routes for innovation

We note that NHS England expects that "…a national supply chain partner will improve access for patients to new technologies…" this ambition is strongly endorsed by industry. Procurement mechanisms need to allow for the introduction of innovation and not impose delays through access to frameworks or any de facto ceiling price on new innovations that deliver improved outcome or system efficiencies.

Payment mechanisms should also support innovations in service delivery. Mandating a single supply route for devices could limit more innovative business models that seek to manage overall costs and reward outcomes and efficiency. Separating consumable, capital and human costs restrict the opportunity to manage service delivery as an entity. We recommend plurality of supply routes within a defined cost envelope.

6. Supporting a competitive market

Price is an important signal to convey information to consumers and producers, we understand that a "zero cost mechanism" is being proposed for providing these devices from NHS England to providers of specialised services. Any procurement process and use of intermediaries needs to ensure that there is a flow of information between manufacturer, supplier and users.

Pre-existing contracts with Trusts should not be over-ridden. Transfer to national procurement contracts should take place upon expiration of pre-existing commercial contracts. Providers were given little notice hence the existence of a number of contracts that overlap with this project. The legal situation and financial benefits to the systems should be addressed on a case-by-case basis.