NHS England drops treatments scorecard following legal threat

19 DECEMBER, 2014 | BY WILL HAZELL HTTP://WWW.HSJ.CO.UK/

NHS England has dropped a controversial scorecard that was supposed to help it make decisions about whether to fund treatments for a number of rare conditions.

It will also launch a 90 day consultation in January on its approach to choosing which treatments to commission, meaning patients will not be able to gain routine access to drugs for months.

NHS England developed the scorecard earlier this year to compare the merits of different treatments, but in a paper presented at its monthly board meeting on Wednesday it confirmed it would not be used in the 2015-16 commissioning round.

The arm"s length body said it would "explore" the idea of a scorecard in 2015, but pledged to undertake a "specific consultation" before any introduction.

NHS England"s decision to drop the scorecard follows thethreat of a judicial review on the basis that the criteria could have disadvantaged patients with rare diseases.

- CCGs poised to defy pharma by switching to cheaper, unlicensed drug
- Appeal finds NICE decision on £90k breast cancer drug „unfair"
- New NHS England partnership with pharma to speed up drug access

The decision was welcomed by the Society for Mucopolysaccharide Diseases, also known as the MPS Society, which supported a patient with the ultra rare disease Morquio, or MPS IVA, to make the legal threat.

However, the decision by NHS England to launch a 90 day consultation next year on its approach to choosing which treatments to fund means it will still be months before patients know whether they will be able to get routine access to drugs.

Christine Lavery, chief executive of the MPS Society, said its victory in getting the scorecard dropped was "bittersweet".

"The ongoing delay means that a number of members who would benefit from treatment are denied access until a funding decision is made," she said.

John Murray, director of the Specialised Healthcare Alliance, said: "To have such an extended consultation… is very worrying from the perspective of patients who have been waiting for decisions in a number of areas for a long, long time already."

A spokeswoman for NHS England said the length of the consultation reflected "the importance of these decisions and advice received from patient groups".

"Any prioritisation which is urgent on clinical grounds will be dealt with quickly through our existing procedures," she added.

Paper NHSE121407

BOARD PAPER - NHS ENGLAND

Title: Investing in Specialised Services
From: Dame Barbara Hakin, National Director: Commissioning Operations
Purpose of paper: • To propose a set of principles which will underpin the decision making process for investment in specialised services. • To outline the characteristics of the process NHS England will use to make decisions on investment in specialised services.
The Board is invited to: • Consider the overall approach proposed in this paper; • Review and approve the proposed principles and procedures as the basis for public consultation; • Authorise the Chief Executive in consultation with the Chair to sign off the consultation paper on behalf of the Board; and, • Delegate the future oversight of these arrangements to the Specialised Commissioning Committee.

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Investing in Specialised Services

1. Before April 2013, commissioning specialised services for the population of England was largely the responsibility of Primary Care Trusts. They acted together in geographical groupings to cover populations of a size more suited for the planning and commissioning of services that typically involve relatively few providers, fewer patients and sometimes unpredictably high costs.
2. From April 2013, NHS England became responsible for commissioning specialised services as defined in Schedule 4 to the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing rules) Regulations 2012. This in effect nationalised the commissioning of a varied portfolio of services and, through the implementation of national service specifications and clinical policies, brought the opportunity to achieve greater consistency and quality for the whole population using these services.
3. NHS England's specialised services portfolio currently costs about £14bn each year, with pressure for substantial growth in activity and costs year on year. Despite the 2014/15 allocation being supported by £400m of non-recurrent funding, the current forecast outturn at month 7 is a deficit of over £150m, mostly associated with the Cancer Drugs Fund. In the context of the Five Year Forward View, the current position and trajectory for spending are not sustainable. The proposed allocation for 2015/16 seeks to eliminate the underlying deficit, however, meeting the needs of the population with the available resources will continue to involve choices and decisions that will be difficult and sometimes controversial.
4. In making its decisions about which specialised services to commission and for whom, NHS England's current process has three principal components. The first is an ethical framework and set of generic commissioning policies. The second is an advisory structure of service-specific Clinical Reference Groups which develop the service specifications and clinical policies to be applied in commissioning. The third is the Clinical Priorities Advisory Group which makes recommendations to NHS England about which treatments and services should be commissioned including priorities for investments.
5. Given that the ethical framework and generic policies were adopted on an interim basis and in the light of a year's experience, in April 2014 work commenced on reviewing our approach to ensure that it is transparent in its criteria and fair in its processes. The work has been shaped with the following in mind:

    - The duty to take investment decisions that are efficient, effective and economically sound, and enable the commissioning of high quality, safe and sustainable services, within the resources available;
    - Our commitment to acting with openness and transparency;
    - The need to make decisions about relative priorities across the whole of the specialised services portfolio; and,
    - The need to meet the needs of the population and reduce inequalities with the resources available.

6. The work has also sought to build on our commitment to good practice with a focus on:

- Clarifying the principles which will underpin commissioning decisions;
- Adopting appropriate and transparent procedures;
- Determining the point in the process where prioritisation assessment is to occur;
- Ensuring timely publication of work plans, decision outcomes, and consultation materials; and,
- Developing further the engagement of patients and the public in the formation of policy proposals.

Proposed principles which underpin decision-making

7. The first step is to establish the relevant principles. To achieve its purpose, the work has been undertaken in partnership with individual patients, patient group representatives, clinicians, commissioners and other stakeholders. A workshop in April 2014 distilled a fresh approach and a reference group was formed to guide and challenge the work. A series of patient and public engagement events contributed to developing the content of the proposed principles to underpin decision-making.

8. The proposed principles fall into four categories:

(i) General principles as to prioritisation:

NHS England will:

- follow its normal good practice in making prioritisation decisions in a transparent way, documenting the outcomes at all stages of the process;
- involve stakeholders including the public in the development of proposals and take appropriate account of their views; and,
- take into account all relevant guidance.

(ii) Does the treatment or intervention work?

NHS England will normally only accord priority to treatments or interventions where:

- there is adequate and clinically reliable evidence to demonstrate clinical effectiveness;
- there is a deliverable and measurable benefit to patients; and,
- they offer equal or greater benefit than other forms of care already in NHS use.

NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available.

(iii) Is the treatment or intervention fair and equitable?

NHS England:

- may accord priority to treatments or interventions for rare conditions even where there is limited published evidence on clinical effectiveness, recognising that the rarity of the condition may make such data unavailable;
- will only prioritise treatments or interventions where these can be offered to all patients within the same patient group (other than for clinical contra-indication).
- will accord priority to treatments or interventions that are likely to reduce health inequalities, and will have regard to any relevant broader equality issues.
- will take into account evidence of the impact of any prioritisation decisions on the wider health and care system, including societal impact.
- will seek to advance parity between mental and physical health.

(iv) Is the treatment or intervention a reasonable cost to the public?

NHS England will:

- prioritise those treatments and interventions that demonstrate the greatest value for money; and
- only commission for those prioritised treatments and interventions that are affordable within its relevant budget, and those that enable resources to be released for reinvestment.

Characteristics of the process for making decisions

9. In prioritising treatments and interventions for the future financial year, NHS England will observe the following sequence.

10. **First Order**. Service investment for NICE Technology Appraisals and the appraisals undertaken as part of the Highly Specialised Technologies Programme. The estimated budget impact for NICE recommended treatments in 2015/16 is in the region of £270M. The decision for this first order is non-discretionary; NHS England is required to fund these NICE appraisals even in the absence of any allocated budget capacity.

11. **Second Order**. There are NHS Constitution delivery requirements which affect specialised services. These include for example the 18-week wait referral to treatment time, and the 14/62-day cancer targets. Most of these requirements are aggregated from local needs analysis building a national investment plan.

12. **Third Order**. Developments to support national service strategies. These may be pre-existing, such as increasing access to transplantation, or nationally or locally defined strategic change. Consideration is given to what treatments and services are provided, to whom and to what level of quality.

13. **Fourth Order**. All other specialised services developments.

14. The Cancer Drugs Fund currently remains outside these arrangements.

15. From the work done since April 2014 to review our current process and practice, we have identified the need to test and develop treatments and interventions that might be commissioned typically using five stages:

- **Environmental Scanning phase,** is coordinated at a Clinical Reference Group level. There are two published outputs from this phase – the list of potential clinical policies that are identified as 'Not being routinely funded' and the list of potential service specifications for commissioning.
- **Planning phase,** where the National Programmes of Care, who coordinate the work of the CRGs into strategic groupings such as Cancer, consider the proposals in the second list and select the ones that most fit the programme's strategic priorities. This will create an Annual Work Programme.
- **Clinical Build phase,** where the Clinical Reference Group works with stakeholders to define the clinical proposal. An independent review of clinical evidence will be commissioned. Finally, a Clinical Appraisal Panel will form a view whether a clinical case is made.
- **Impact Analysis and Consultation phase,** where NHS England will develop, using the defined clinical criteria, a service impact analysis and hence a financial impact analysis. This will result in a final policy or service specification that can be considered for commissioning. The scale and duration of consultation will then be defined.
- **Governance phase,** where the Clinical Priorities Advisory Group assures the Board that the process has been completed and recommends a priority order of commissioning. The NHS England Board approves the prioritisation. Commissioning against the priorities will be overseen by the Specialised Commissioning Committee.

16. The detail of the five phases, including the process step summaries, will be available in the consultation supporting documents. Embedded within the process are a number of steps where decisions will be made. Each of these will be defined as 'Decision Making Events' and detail the elements such as who makes the decision, how the decision is made, and how the decisions are communicated.

17. One of the components under consideration to aid decision-making is the formation of a scorecard methodology. As part of the process for developing a prioritisation framework for specialised commissioning, NHS England will explore in 2015 the extent to which a 'scorecard' would be an appropriate tool to deploy in the proposed prioritisation process. If as a result of this further work a scorecard is considered ready for inclusion in the decision making processes in future years, then a specific consultation will be undertaken before introduction. The prototype scorecard developed and tested earlier this year will not be used in the 2015/16 commissioning round.

The Proposed Consultation

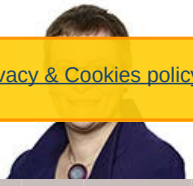
18. We propose to launch a public consultation about the principles and approach to decision-making from January 2015. The Specialised Commissioning Committee will receive the consultation report on behalf of the Board and review the proposed principles and process in light of the consultation responses.

Conclusion

19. The Board is invited to:

- Consider the overall approach proposed in this paper;

- Review and approve the proposed principles and procedures as the basis for public consultation;
- Authorise the Chief Executive in consultation with the Chair to sign off the consultation paper on behalf of the Board; and,
- Delegate the future oversight of the process to the Specialised Commissioning Committee.



CCGs poised to defy pharma by switching to cheaper, unlicensed drug

27 November, 2014 | By Sarah Calkin

Clinical commissioning groups across England are mulling the use of an unlicensed drug which could save the NHS millions of pounds, *HSJ* has learned.

Vale of York and Northern, Eastern and Western Devon CCGs are hoping to switch from Lucentis to Avastin for the treatment of age related macular degeneration, as are a number of other CCGs across the North East.

While both drugs are closely related, Avastin is listed at a 10th of the price of Lucentis.

The cheaper drug is licensed by the Medicines and Healthcare Products Regulatory Agency for the treatment of five cancers in their advanced stages, including breast and lung cancer but is not licensed for use in the eye.

Controversy over its use to treat age related macular degeneration has raged for years.

In 2012, Novartis which markets the drug in the UK, launched a judicial review of a primary care trust cluster's plans to mandate its use.

CCGs have revisited the issue after a Cochrane review concluded that use of the cheaper drug was safe.

Vale of York chief clinical officer Mark Hayes told *HSJ* the main barrier to the routine use of Avastin in the UK was the General Medical Council's code.

- New NHS England partnership with pharma to speed up drug access
- Cancer drugs fund threatens NHS England's bottom line
- NHS England could curb access to NICE approved drug

This stipulates that doctors should not use unlicensed drugs unless they think it is the best option for "medical reasons".

"Absolutely everyone knows [using Avastin] is the right thing to do but clinicians are afraid of the GMC and the government don't want to upset the drug companies," he said.

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Dr Hayes said Avastin was available for a 10th of the Lucentis £600 listed price.

While *HSJ* understands Lucentis is offered at a significant discount on the list price, the CCG estimates it could save £4m annually by switching to the cheaper drug.

The Health and Social Care Information Centre estimates the NHS spent almost £244m on Lucentis in 2013-14, the second largest amount the NHS spent on a drug.

Vale of York CCG is due to be asked next week to approve the preparation of a business case for the provision of an Avastin only service from next April.

The move is also one of a raft of initiatives being considered by NEW Devon as part of its drive to find £26m of in-year savings.

Alistair Blair, an NHS Clinical Commissioners board member and chief clinical officer of Northumberland CCG, said lots of CCGs in the North East were also looking into the issue.

Dr Blair told *HSJ* that one approach under consideration was informing patients of the cost difference and allowing them to make a choice.

"I can't see many patients saying they want the more expensive drug if you look at the evidence available," he said.

Only manufacturers can ask regulators to consider licencing a drug for the treatment of particular conditions.

Roche, which owns the patents for both drugs, has not done so.

In a statement, the company said it was not licensed because it had not been "developed and manufactured to meet intraocular standards".

However, in February this year Novartis and Roche were each fined more than €90m by the Italian Competition Authority for colluding to maintain an "artificial distinction" between the two drugs.

In 2010 the National Institute for Health and Clinical Excellence recommended the Department of Heath request an appraisal of Avastin for the treatment of wet age related macular degeneration.

NICE cannot consider this until the DH makes a formal referral, which it is yet to do.

During health questions in the Commons on Tuesday, minister for life sciences George Freeman said the decision to prescribe unlicensed drugs was for clinicians.

"I don't think it's right that the government gets into the position of effectively sponsoring new licencing requests," he said.

A spokeswoman for the GMC said its guidance was "consistent with European law" which states that "it is unlawful to prescribe unlicensed medicines - including for a condition not covered in the license - on the grounds of cost".

"Clearly we cannot issue guidance that might lead doctors to act unlawfully," she added.

Readers' comments (11)

Anonymous | 27-Nov-2014 1:38 Pm

This is something that NICE and Bruce Keogh should be leading on.
It is not fair to expect local CCGs to take the heat for this tricky decision.

Unsuitable or offensive?

Anonymous | 27-Nov-2014 2:24 Pm

This drug is used in private practice up and down the country however its only the NHS who are nervous of using it and Pharma want to retain mononploly and not seee their profits cuts.Shame on Pharma!

Unsuitable or offensive?

Anonymous | 27-Nov-2014 2:41 Pm

A PCT in a challenged health system spent several months 4 years ago trying to implement this. The clinicians refused, quoting Royal College & NICE guidance - despite evidence that the clinician used it already for his private patients, with no obvious qualms.

Pharma do need to be reined in, and this is an obvious place to start acting as a National health system

Unsuitable or offensive?

Anonymous | 27-Nov-2014 5:52 Pm

As per the comment at 1.38, this is something that would benefit from a national approach; its simply a waste of clinicians time at a local level to have the same debate as their colleagues across the country, there are more pressing,controversial and complex clinical issues that need clinicians time and effort.

Unsuitable or offensive?

Anonymous | 27-Nov-2014 6:55 Pm

I have been injected with Avastin privately for my eye because the dear old PCT refused to fund Lucentis because of its costs. When I heard that Avastin was used for bowel cancer, I told the consultant that it was two for the price of one.

Unsuitable or offensive?

Anonymous | 27-Nov-2014 7:33 Pm

Not sure that "shame on pharma" case is conclusive, but it is interesting that Roche (Avastin's producer) is not seeking to get it licensed. I would love to hear their reasons.

Unsuitable or offensive?

Anonymous | 28-Nov-2014 9:24 Am

I imagine the reason they would give is that the cost of trials to get it licenced for a very different indication would be

prohibitively expensive, given the potential market size and the fact that they already have the dominant drug in that market. From a business perspective it would make no sense for them to pursue the licence. There needs to be a way that someone else could sort the trials and apply for the licence, but I think currently only a patent holder can apply for a licence (even if other do trials).

Unsuitable or offensive?

Anonymous | 28-Nov-2014 12:55 Pm

...many CCGs are already doing this as quietly as possible...

Unsuitable or offensive?

Christine Blanshard | 4-Dec-2014 2:57 Pm

I am the medical director of a smallish acute Trust that tried to do this, with the support of our ophthalmologists and our commissioners, back in 2011-12. All was going well until we received a letter before claim from lawyers acting for Novartis. At the time the company was pursuing a judicial review of the decision of four local PCTs to promote the prescription of Avastin rather than Lucentis, and we were advised by our solicitors to cease with immediate effect or we would incur prohibitive legal fees in defending our action. We have not dared to try again since.

Unsuitable or offensive?

George Webb | 10-Dec-2014 1:54 Pm

Does anyone in The NHS know what the chemical difference is between the two drugs ignoring whatever inactive constituents are present. Any takers?

Unsuitable or offensive?

Anonymous | 15-Dec-2014 11:22 Am

Hello George. I am an NHS scientist. Both are monoclonal antibodies. Lucentis is smaller than Avastin and it was thought the larger size of Avastin meant it couldn't penetrate the retina as effectively in order to work. Lucentis has one binding site and Avastin has two, but Lucentis is formulated for injection into the eye and Avastin for intravenous injection (the manufacturing process is more stringent). Both are made from the same mouse antibody precursor but Lucentis has extra affinity ligands (things which make something stick to something else). Their half lives are also different, I.e. How long they're effective for. Avastin lasts longer than Lucentis but this storage in cells can cause longer term problems. My family member has AMD and I would want her to have Lucentis and politely suggest that the NHS find other ways of saving money.

Unsuitable or offensive?

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Appeal finds NICE decision on £90k breast cancer drug 'unfair'

16 December, 2014 | By Sarah Calkin

The impact of the government's drug pricing deal on patient access to new medicines has been thrown into confusion after a pharmaceutical company's appeal against the decision to ban routine NHS funding of one of its drugs was upheld.

New NHS England partnership with pharma to speed up drug access

21 November, 2014 | By Sarah Calkin

Government plans for closer working between the NHS and the pharmaceutical industry will make the new generation of precision medicines more affordable for the NHS, the minister for life sciences has said.

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