

BI1 Improving HCV Treatment Pathways through ODNs

Scheme Name	Hepatitis C Virus (HCV) Improving Treatment Pathways through Operational Delivery Networks (ODNs)
Eligible Providers	<p>Priority CQUIN for all HCV Operational Delivery Network Lead providers as follows:</p> <p>LEAD PROVIDER</p> <ol style="list-style-type: none"> 1. The Newcastle Upon Tyne Hospitals NHS Foundation Trust 2. Pennine Acute Hospitals NHS Trust & Central Manchester University Hospital Trust 3. Royal Liverpool & Broad Green University Hospital NHS Trust 4. Sheffield Teaching Hospitals NHS Foundation Trust 5. Hull & East Yorkshire NHS Trust 6. Leeds Teaching Hospitals 7. East Lancashire Hospital NHS Trust 8. University Hospitals of Leicester 9. University Hospitals Birmingham NHS Foundation 10. Nottingham University Hospitals NHS Trust 11. Cambridge University Hospitals NHS Foundation Trust 12. Imperial College Healthcare Trust 13. Royal Free London NHS Foundation Trust 14. Barts Health 15. Kings College Hospital NHS Foundation Trust & St George's University Hospitals NHS Foundation Trust 16. Royal Surrey County Hospital NHS Foundation Trust 17. Brighton & Sussex University Hospitals 18. Oxford University Hospitals NHS Foundation Trust 19. University Hospital Southampton NHS Foundation Trust 20. University Hospitals Bristol NHS Foundation Trust 21. Plymouth Hospitals NHS Trust 22. Kings College Hospital NHS Foundation Trust
Duration:	April 2016 – March 2019
Scheme Payment	<p>Two elements:</p> <ol style="list-style-type: none"> 1. Governance and Partnership Working: £100,000 per network. Where 2 providers share lead status the split of this funding to be agreed with commissioner and the 2 providers. 2. Stewardship and NICE compliance 1.6% of provider's overall CQUIN applicable specialised contract value <p>2017/18 Target Value: Add locally</p> <p>2018/19 Target Value: Add locally</p>

Scheme Description

This CQUIN supports the infrastructure, governance and partnership-working across healthcare providers working in HCV networks in their second and third years of operation to achieve the following outcomes:

- Improvements in engagement of patients
- The planned rollout, aligned to NICE guidance, of new clinical and cost effective treatments guidance to improve outcomes through Multi-disciplinary team treatment plans
- Improved participation in clinical trials
- Enhanced data collection to demonstrate the effectiveness and equity of this way of working and the availability of new treatments.

Providers across networks are responsible for developing a working group for this CQUIN scheme, mapping patient pathways and producing a plan to improve partnership working. By the end of the CQUIN scheme, ODNs will:

- a. Be part of ongoing HCV clinical care as set out by NICE in published and forthcoming technology appraisal guidance, with all patients receiving Hepatitis C care benefiting from ODN policy-compliant care approved by an MDT
- b. Have clear and fully understood arrangements for partnership working inclusive of local patient groups and providers. There should be a clear written plan for partnership working with clarity of responsibility. There should be agreed communications about the ODN which allow professionals and patients alike to understand how the ODN operates and how to contact it
- c. Have developed partnerships which involve providers, commissioners, voluntary organisations and patients
- d. Provide clear monitoring data on ODN operation and outcomes for patients, including the impact of the ODN model for improving access and real life effectiveness of new treatments. This should contribute to public health, activity, outcomes and experience monitoring needs
- e. Be actively involved in opportunities to share learning and develop solutions within and across ODNs at regional & national level, to build the ODN collaboration model.

Measures & Payment Triggers – Governance Payment

Where year one triggers were not met in year one they should be included by local amendment for year two.

I. Quarter 1 Achievement: (25% of Governance Payment)

- a. **Baseline report** (Year one) including: signed ODN arrangements by all partners; governance arrangements; ODN footprint map including CCG boundaries and provider partners; current baseline of pathways and services; gaps in service provision; populations in line with policy / NICE guidance; evidence of appropriate administrative arrangements to enable MDTs / data reporting
- b. **Engagement plan** (Year one) for regional and national ODN network, and for voluntary sector & patients.
- c. **Pathway Mapping Group** (Year one) established (membership confirmed, schedule of meetings).
- d. **Dataset reporting arrangements*** (Year one) for all partners clarified and implementation begins.
- e. **Proposals to monitor incidence and re-infection rates** (Year one) in a defined subset of treated patients at risk of re-infection
- f. **Progress Report** (Year two and three)

II. Quarter 2 Achievement: (25% of Governance Payment)

- a. **Develop partnership model and plan** (Year one) for implementation and submit to NHS England for comments. This to involve non specialised providers and relevant commissioners.
- b. **Dataset reporting* fully implemented.** (Year one) **Complete reporting** (Year 2,3)
- c. Evidenced commencement of **5 year ODN plan** development. (Year one)
- d. **Progress report** (Year two and three)

III. Quarter 3 Achievement: (25% of Governance Payment)

- a. Implementation of the improved **partnership model** and partnership working including systems for data collection, activity and incidence monitoring. (Year One)
- b. Process undertaken to **assess patient experience.**(Year One)
- c. **Communication and engagement plan** agreed (Year one).
- d. **Complete dataset reporting*** in the quarter.
- e. **Progress Report** (Year two and three)
- f. **ODN Five Year Plan Objectives Refresh** (Year Two and Three)

IV. Quarter 4 Achievement: (25% of Governance Payment)

- a. **Annual report** of ODN operation submitted including progress on governance, partnership working, activity reporting & patient experience feedback.
- b. **Map of pathways /services** published. (Year one)
- c. **ODN 5 year plan** submitted and includes detailed plans for 17/18 priorities and objectives. To include how services and access to be improved for relevant patient groups. Implementation of communication and engagement plan.
- d. **Complete dataset reporting*.**
- e. **Progress Report** (Year two and three)

Where necessary to fulfil responsibilities providers may use funding from both the governance and stewardship payment to ensure network operation is adequately resourced to fulfil responsibilities for its own patients as well as its role as undertaking independent expert review for 'prior approval' patients for another assigned ODN.

Measures & Payment Triggers – Stewardship Payment

A NEW LONGER TERM INDUSTRY AGREEMENT FOR FUNDING DAA TREATMENTS IS EXPECTED TO BE CONCLUDED BY APRIL 2017. STEWARDSHIP PAYMENT TRIGGERS WILL BE REVISED TO ALIGN WITH THIS AGREEMENT, AND TREATED AS A LONGSTOP IN THE NHS STANDARD CONTRACT

TRIGGER A: Managed resources within indicative financial budget forecast

- Each ODN will be issued an indicative forecast financial budget on a half yearly basis. Based on the published run rate for each ODN, and the confidential region-specific prices for HCV treatment options clinically appropriate to each genotype and treatment history, inclusive of fees, taxes and charges.
- To avoid localised differences in populations (such as differing genotype profiles by ethnicity) impacting on assessment of this measure, performance against indicative financial forecast of all 22 networks will be reported individually but risk pooled.
- Where the combined committed spend for the half year is less than or equal to the indicative budget, the full 1.6% incentive will be available to every ODN paid on the basis

of the triggers B1 to B4 below

- Where the combined committed spend for the half year exceeds the indicative budget, the incentive available to every ODN and paid on the basis of the triggers B1 to B4 below will be reduced on a £ for £ basis.

TRIGGER B1: ODN MDT decisions aligned to NHS England published run-rate

- One fifth of the stewardship incentive available through trigger A is payable provided the ODN delivers MDT treatment initiations in line with the published run rate for the half year. To qualify for payment the ODN treatment rate must be not less than 90% and not more than 100% of the published half year rate. There is no payment for partial achievement of this element.

TRIGGER B2: ODN Treatment cost per patient relative to lowest acquisition cost

- One fifth of the stewardship incentive available through trigger A is payable through this trigger. The indicative financial budget incorporates valid clinical exceptions to lowest acquisition cost and will be reviewed twice yearly.
- Each ODNs lowest acquisition cost measure will be adjusted for genotype, cirrhosis status and treatment history of patients initiated.
- Where the ODN average treatment cost per patient is within 10% of lowest acquisition cost for the network this indicator will be paid in full.
- Where average treatment cost per patient is above 10% of lowest acquisition the 6 networks with highest % variance will receive no payment; the remaining networks will receive half payment

TRIGGER B3: ODN Prioritisation of patients with highest clinical need

- One fifth of the stewardship incentive available through trigger A is payable through this trigger. Each ODN will set out its local priorities within its baseline report in Quarter one, including the objective criteria by which they will assess achievement of these aims. NHS England regional clinical directors, with advice from public health England and the national clinical ODN lead will assess the network Annual report and the supporting data for evidence that the network has been actively implemented. Data may include the levels of patients initiated with cirrhosis, fibrosis F3 or above, or with relevant comorbidities, and reaching particular patient subgroups relevant to local health needs.
- Where the ODN shows strong evidence of meeting active plans for prioritising highest clinical need it will receive full payment of this element. A partial payment of 75% of this element will be paid where evidence provided gives limited assurance that patients with highest clinical need have been prioritised.

TRIGGER B4: ODN Effectiveness in sustaining benefits of treatment

- One fifth of the stewardship incentive available through trigger A is payable through this trigger. Evidence about reinfection rates is not yet sufficiently developed to use as the basis of incentivisation, so this measure incentivises capturing and analysing ODN data about local incidence of reinfection from follow up testing 48 to 60 weeks after treatment completion and using insights to inform clinical practice interventions to promote reduction of patient risk factors.

- Where evidence is gathered for over 85% of patients treated in the preceding 60 weeks and a report identifying trends and applying learning to treatment practices of the ODN is published full payment of this element will be made.
- Where evidence is gathered for less than 50% of patients treated, no payment will be made
- Where the proportion of patients retested for whom data is captured falls between 50 and 85% and a report identifying trends and applying learning to treatment practices of the ODN is published, the payment for this element will be proportional to the % of patients for whom retest data is captured.

TRIGGER B5: Completeness and Data Quality in the ODN 'registry'

- One fifth of the stewardship incentive available through trigger A is payable through this trigger.
- This payment is made where the ODN has a plan for getting all patients known to services (including those yet to be treated) to have an accurate entry in the registry within 4 months of the registry being made available by Public Health England.
- Full payment will be made where data is above 85% complete and warranted as accurate by the clinical lead in each partner organisation within 4 months and maintained each month thereafter.
- No payment will be made where data which is complete and warranted as accurate is below 50%
- Where between 50% and 85% of data is complete and warranted as accurate the payment for this element will be proportional to the % achieved

Definitions

1. MDT Treatment

- a. Numerator: No of HCV patients whose treatment has been subject to MDT review and accords with ODN guideline.
- b. Denominator: No of HCV patients in catchment population that should be seen in period (set out in MDT plan for network agreed with commissioners)

2. Supporting Indicators

- a. Average Drug Treatment Plan Duration (weeks)
- b. % patients completing treatment as planned
- c. Patients drug treatments initiated by genotype and fibrosis/Cirrhosis status

3. Dataset Reporting As described and as specified in supporting documentation: BI1 Hepatitis C CQUIN reporting requirements.docx

4. Registry data completeness

The denominator for number of patients for this measure is as follows: The number of RNA positive patients who have attended clinic at all providers within the ODN and have not been discharged after treatment, as extracted from provider clinic systems.

The supporting information for measures which relate to confidential prices of treatments are available directly to ODN lead providers on a commercial in confidence basis and should only be shared as needed with ODN partner organisations who are party to a confidentiality agreement. Further information will be provided to ODN lead providers.

Partial achievement rules	
The governance payments are per quarter with no partial payment if not achieved. The stewardship payments partial achievement rules are set out in the measures and payment triggers section	
In Year Payment Phasing & Profiling	
Governance payments are quarterly. Stewardship payments are half yearly for B1 to B3 and full year end for B4 and B5	
Rationale for inclusion	
New HCV Treatments are recognised to be cost effective by NICE, and ODNs are a specified element of NICE technology appraisal guidance. The operation of managed network principles can <ul style="list-style-type: none"> - Ensure clinically appropriate medicine choice and treatment duration is selected in line with latest evidence, and maximise the access to treatment relative to investment, achieving greater health gain. - Ensure patient treatment interventions maximise adherence to treatment regimen and minimise relapse thus minimising the reduction in health outcomes for real world treatment compared to trial conditions - Provide an equitable basis to rollout and prioritise patients with highest clinical need. 	
Data Sources, Frequency and responsibility for collection and reporting	
Two types of data requirement: <ul style="list-style-type: none"> • Narrative reports – produced by ODN Clinical Teams • Dataset: This is demonstrated via 3 sources – Blueteq, drugs MDS and HCV outcomes dataset all of which must be fully completed and complied with <p>Providers will need to produce evidence of appropriate administrative arrangements in place to enable MDTs / data reporting.</p>	
Baseline period/ date & Value	Not Applicable – performance based on MDT plan not baseline period: MDT Plan Activity for financial year
Final indicator period/date (on which payment is based) & Value	Measures for financial year as at Month 6 and Month 12 except where otherwise stated
Final indicator reporting date	Month 12 Contract Flex reporting date as per contract
CQUIN Exit Route <i>How will the change including any performance requirements be sustained once the CQUIN indicator has been retired?</i>	The set up costs of HCV ODNs were supported financially in ETO provider CQUIN or central funding allocation in 2015/16. As a year 2 and year 3 CQUIN, the governance costs will be embedded in reference costs from the year after the CQUIN concludes. Governance arrangements will need to reflect funding flows needed from Tariff income in year 4 across partner organisations to fund ongoing network infrastructure. The future of stewardship payments will be reviewed in light of developments during 2017 and 2018.

Supporting Guidance and References

NICE has concluded that a number of new oral HCV treatments are cost effective for certain patient groups (see <https://www.nice.org.uk/guidance/conditions-and-diseases/liver-conditions/hepatitis>)

Reducing harm from Hepatitis C is a priority for the NHS. There are estimated to be 160,000 people with chronic Hepatitis C infection in England, of whom 80,000 are diagnosed. In 2012 about 5000 people received drug treatment for HCV in the UK, i.e. about 3% of the prevalent pool of infected patients receives treatment each year. A wide body of literature on generalisability of healthcare research suggests treatment adherence and clinical outcomes achieved in real world settings fall short of clinical trial based outcomes (For example Sculpher et al 2004¹) Effective clinical networks are one way to minimise this shortfall.

NHS England has implemented the establishment of Hepatitis C networks to ensure clinical and cost effective care is delivered with oversight from Hepatitis C centres and MDTs. Strong partnership working across the complex pathways for patients is essential to ensure patients have access to both clinical expertise and local delivery of care.

There are a large number of commissioners and services involved in the treatment of patients who may have Hepatitis C or are infected and also suffer from other co-morbidities or conditions. Acute services, drug and alcohol services, detained settings, primary and community care providers may be caring for the eligible patient groups. The majority of patients with Hepatitis C are within disadvantaged groups.

The CQUIN scheme is linked to the development of a national group of ODNs which will help support clinicians with identifying the most clinically and cost effective options for patients. It will spread specialist expertise in this rapidly evolving field beyond specialist centres making it more accessible for patients and ensuring all have access to the appropriate therapeutic options and greater integration of care between providers of services whilst preserving local access.

Treatment selection is complex to support adherence, avoid resistance and relapse and to make best use of NHS resources. Hepatitis C ODNs provide a vehicle for ensuring that clinicians are aware of which are the most cost effective, efficacious treatments and to help choose between alternative products and treatment plans
England has lacked any national data linking across services to improve accuracy of data on patient numbers, treatment, outcomes and access. This CQUIN scheme supports the innovation required by the whole system to work together to manage access to new treatments in a cost effective way. Networks are expected to play an active role in developing and refining the outcome data collected by partner providers over the next 2 years to develop the evidence base of treatment in routine clinical practice

¹ Sculpher MJ, Pang FS, Manca A et al. Generalisability in economic evaluation studies in healthcare: a review and case studies. Health Technology Assessment 2004; 8:1-206. See also Drummond MF, McGuire A eds. Economic Evaluation in Health Care: Merging Theory with Practice. Oxford University Press