

- Title** Modification of the Nomenclature of Procedures in Laboratory Medicine for the procedure for therapeutic monitoring of patients infected with *Treponema pallidum* (bacterium responsible for syphilis)
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- Reference** link to full report in French: http://www.has-sante.fr/portail/jcms/c_2752929/fr/modification-de-la-nomenclature-des-actes-de-biologie-medicale-pour-l-acte-de-suivi-therapeutique-des-patients-infectes-par-treponema-pallidum-bacterie-responsable-de-la-syphilis

Aim

The purpose of this work is to respond to a request of the Caisse nationale d'assurance maladie des travailleurs salariés (CNAMTS [National Health Insurance fund for salaried workers]) made in June 2014, with a view to including a procedure for therapeutic monitoring of syphilis in the Nomenclature of Procedures in Laboratory Medicine (NABM).

Following this same request, an assessment of screening and diagnostic procedures was published in May 2015.

The CNAMTS proposes including a therapeutic monitoring procedure based on a quantitative nontreponemal test (NTT), which should be carried out 3, 6 and 12 months after the start of treatment for early syphilis (and more frequently in HIV-infected patients and pregnant women) and 6, 12 and 24 months after the start of treatment for late syphilis. The request states that a negative result, or else a four-fold decrease in titre, confirms a cure, while a four-fold increase in titre allows the diagnosis of a re-infection.

Conclusions

The six documents analysed recommend monitoring of the treatment of early syphilis by means of a quantitative NTT assay. Monitoring of late syphilis must also be done by quantitative NTT assay, according to five of the six documents. Therefore, these conclusions are very largely in agreement with the proposed modification suggested by the CNAMTS.

Three of the six documents specify the frequencies of therapeutic monitoring. These frequencies are inconsistent between the documents. It should be noted that the monitoring frequency proposed by the CNAMTS is very similar to the frequency proposed by one of these three recommendations.

A specific treatment monitoring in pregnant women and HIV-positive patients is specified in three of the six documents. There is a relative agreement between these three documents and the request as regards the implementation of more frequent monitoring in these two populations.

Finally, there is agreement between the six documents analysed and the request on the subject of NTT thresholds for concluding success, failure or re-infection (a minimum four-fold variation).

It should be noted that the CNAMTS proposal corresponds in all respects to the current position of the French National Reference Centre for syphilis, with regard to monitoring of early syphilis, frequency of monitoring and methods for monitoring pregnant women and HIV-positive patients. On the other hand, the French National Reference Centre does not mention the methods for monitoring of late syphilis.

In summary, given the data analysed, HAS issues a favourable opinion regarding the proposal of the CNAMTS for registration of this syphilis treatment monitoring procedure in the NABM.

Methods

The assessment method involved a critical analysis of the summary literature (good practice guidelines and technological assessment reports), identified by a systematic literature search for the period 2007-2017, and took into consideration the position of the French National Reference Centre for syphilis, through its written recommendations published on its website.

Five good practice recommendations and one technological assessment report were analysed for the purpose of the present report.

Their authors emphasize the scarce amount of good quality data available. Their recommendations are based on data with a low level of evidence or on expert opinions; those concerning the actions to take for therapeutic monitoring are never graded.

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