Senate Community Affairs references Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients

20 April 2016

Question no: 1

Topic: Pathologists

Type of Question: Hansard, page 8

Senator: Senator Wang

Question:

Senator WANG: I have another follow-up. Given that the cause of the Lyme-like illness in Australia is a bit of an unknown, would it be prudent for the department, or whoever controls the guidelines, to loosen the rules a bit so that the pathologists who are working on the ground, dealing with the blood samples, can do a couple more tests if they feel that is required, and so that we have the ability to collect more data from the people who are working on the ground? Would that be possible?
Dr Lum: That is not an area within the department that I work in, but I do know that that particular area, the Medical Benefits Division, is currently undertaking a review of the Medicare Benefits Schedule, and that is probably an important question that should be put to it.

Answer:

While there is a legislative mechanism that allows pathologists to undertake more tests than originally requested (in limited circumstances and for a restricted number of tests) it does not apply in this case. This is referred to as a pathologist-determinable service. For tests to be included as pathologist-determinable a test must be listed on the Medicare Benefits Schedule (MBS), and the Minister must consult with the Royal College of Pathologists of Australasia for clinical advice and its agreement on how the test should be used in particular circumstances.

There are a number of tests listed on the MBS which may be used to detect the presence of antibodies produced in response to infection. Should a person return from international travel with symptoms of a Lyme-like illness, their treating doctor can order testing which pathologists may perform under a range of items listed in Group 3 (Microbiology) of Category 6 (Pathology Services Table) of the MBS. The usual requesting framework applies, that is, tests are ordered as deemed clinically relevant by the treating clinician, and the pathologist conducts testing as requested. The applicable items and rebates are listed at Attachment A.

Attachment A

Item Number	Item Descriptor
69384	Quantitation of 1 antibody to microbial antigens not elsewhere described in the Schedule – 1 test (This fee applies where a laboratory performs the only antibody test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA). (Item is subject to rule 6) **Fee:** $15.65 **Benefit:** $11.75
69387	2 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 2 estimations specified on the request form or performs 2 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA). (Item is subject to rule 6) **Fee:** $29.00 **Benefit:** $21.75
69390	3 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 3 estimations specified on the request form or performs 3 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA). (Item is subject to rule 6) **Fee:** $42.35 **Benefit:** $31.80
69393	4 tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 4 estimations specified on the request form or performs 4 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA). (Item is subject to rule 6) **Fee:** $55.70 **Benefit:** $41.80
69396	5 or more tests described in item 69384 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 5 estimations specified on the request form or performs 5 of the antibody estimations specified on the request form and refers the remainder to the laboratory of a separate APA). (Item is subject to rule 6) **Fee:** $69.10 **Benefit:** $51.80
69400	A test described in item 69384, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP – 1 test. (Item is subject to rules 6 and 18) **Fee:** $15.65 **Benefit:** $11.75

69401	A test described in item 69384, other than that described in 69400, if rendered by a receiving APP – each test to a maximum of 4 tests. (Item is subject to rules 6 and 18) **Fee:** $13.35 **Benefit:** $10.05
69494	Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified). 1 test. (Item is subject to rules 6 and 26) **Fee:** $28.65 **Benefit:** $21.50
69495	2 tests described in 69494 (Item is subject to rules 6 and 26) **Fee:** $35.85 **Benefit:** $26.90
69496	3 tests described in 69494 (Item is subject to rules 6 and 26) **Fee:** $43.05 **Benefit:** $32.30
69497	A test described in item 69494, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP – 1 test. (Item is subject to rules 6, 18 and 26) **Fee:** $28.65 **Benefit:** $21.50
69498	A test described in item 69494, other than that described in 69497, if rendered by a receiving APP – each test to a maximum of 2 tests. (Item is subject to rules 6, 18 and 26) **Fee:** $7.20 **Benefit:** $5.40

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Question no: 2

Topic: ME/CFS clinical practice guidelines

Type of Question: Hansard, page 10

Senator: Senator Ludlam

Question:

Senator LUDLAM: I have missed a couple of hearings. I missed the Brisbane hearing. In the case of the broader categories around ME/CFS—and you can touch on Lyme and Lyme-like symptoms, if you like—when were the guidelines due to be updated? When did that five- or 10-year cycle lapse?
Prof. Kelso: I am not aware that we have a set of clinical guidelines specifically for Lyme disease or similar syndromes.
Senator LUDLAM: I might ask you to take that on notice. My understanding is that the CFS guidelines were due to be updated at the end of June 2014. Does that sound familiar?
Prof. Kelso: I am afraid I do not know, but I can find that out.

Answer:

Other than the Department of Health's *An Australian Guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosi*s, NHMRC is unaware of any Australian clinical practice guidelines for Lyme disease.

NHMRC has not been approached to develop guidelines for ME/CFS, nor has it been asked to approve evidence-based guidelines developed by third parties according to NHMRC's guideline development standards.

There are no current Australian ME/CFS clinical practice guidelines on the NHMRC's clinical practice guidelines portal (clinicalguidelines.gov.au).

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20 April 2016

Question no: 3

Topic: International Consensus Primer on ME/CFS

Type of Question: Hansard, page 10-11

Senator: Senator Ludlam

Question:

Senator LUDLAM: Put that one on notice as well. I am interested to know what the status is of those at the present time, because my understanding—I could be wrong; I am very happy for you to go back and take a look at what is going on behind the scenes—is that Emerge Australia, the Griffith University research team at NCNED, endorsed the international consensus criteria. I am trying to work out what the state of play is here in Australia at the moment.
Prof. Kelso: I am sorry. I do not know the answer to that question at this stage, but we will find out what we can.
Senator LUDLAM: I am bringing those international consensus criteria up because it does mean a faster diagnosis for patients—and less of a burden on the health system, but particularly for patients—but it will specifically preclude graduated exercise therapy and cognitive behavioural therapy as a helpful treatment for people with these symptoms. Does that sound familiar to you?
Prof. Kelso: I have not read the guidelines and I am not familiar with the clinical guidelines at all. I am sorry. I should be clear in saying that, as CEO of NHMRC, I am not personally involved in the development of guidelines, but I oversee the process of those guidelines which we have been charged with developing or with reviewing and updating. I am then in charge of that overall process, but an expert working group would be familiar with all the detail and be able to answer those sorts of questions.
Senator LUDLAM: Could you please provide us with some that detail. My information is that there has been a fairly significant breakdown in the way that people are being diagnosed at the moment.

Answer:

The former CEO of ME/CFS Australia (now Emerge Australia) met with NHMRC in October 2013 to discuss plans to develop Australian guidelines, and seeking NHMRC's assistance in disseminating them on the NHMRC's clinical practice guidelines portal. However to NHMRC's knowledge no such guidelines have yet been developed.

NHMRC is aware of the 2012 International Consensus Primer on ME/CFS. However it does not meet the criteria for inclusion on the NHMRC's portal as an evidence-based clinical practice guideline.

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20 April 2016

Question no: 4

Topic: Trials in Norway

Type of Question: Hansard, page 11

Senator: Senator Ludlam

Question:

Senator LUDLAM: Norwegian scientists have found an immune-modulating drug called rituximab, which is in a phase 3 trial in Norway with the results due at the end of 2017-18. Can you please outline the process of initiating a trial of that drug in Australia for ME/CFS patients?

Answer:

There are two schemes under which clinical trials involving therapeutic goods may be conducted, the Clinical Trial Exemption (CTX) Scheme and the Clinical Trial Notification (CTN) Scheme. These schemes are used for clinical trials involving:

- any product not entered on the Australian Register of Therapeutic Goods; or
- use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval.

Clinical trials in which registered medicines are used within the conditions of their marketing approval are not subject to CTN or CTX requirements but still need to be approved by a Human Research Ethics Committee (HREC) before the trial may commence.

The CTN Scheme is a notification scheme.

- All material relating to the proposed trial, including the trial protocol is submitted directly to the HREC by the researcher at the request of the sponsor. The TGA does not review any data relating to the clinical trial. The HREC is responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device and the ethical acceptability of the trial process, and for approval of the trial protocol. The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.
- CTN trials cannot commence until the trial has been notified to the TGA and the appropriate notification fee paid.

The CTX Scheme is an approval process.

- A sponsor submits an application to conduct clinical trials to the TGA for evaluation and comment. A TGA Delegate decides whether or not to object to the proposed Usage Guidelines for the product. If an objection is raised, trials may not proceed until the objection has been addressed to the Delegate's satisfaction.
- If no objection is raised, the sponsor may conduct any number of clinical trials under the CTX application without further assessment by the TGA, provided use of the product in the trials falls within the original approved Usage Guidelines. Each trial conducted must be notified to the TGA.
- A sponsor cannot commence a CTX trial until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted. There are two forms, each reflecting these separate processes (Parts), that must be submitted to TGA by the sponsor.
- Part 1 constitutes the formal CTX application. It must be completed by the sponsor of the trial and submitted to TGA with data for evaluation.
- Part 2 is used to notify the commencement of each new trial conducted under the CTX as well as new sites in ongoing CTX trials. The Part 2 form must be submitted within 28 days of the commencement of supply of goods under the CTX. There is no fee for notification of trials under the CTX scheme.

All CTN and CTX trials must have an Australian sponsor. The sponsor is that person, body, organisation or institution which takes overall responsibility for the conduct of the trial and signs either the CTN form or the CTX form. The sponsor usually initiates, organises and supports a clinical study and carries the medico-legal responsibility associated with the conduct of the trial. The sponsor of a clinical trial for an extension of indications for an already registered medicine, such as the use of rituximab in ME/ CFS patients, is usually the company which is considered to be the sponsor of the product on the Australian Register of Therapeutic Goods.

All clinical trials in Australia require review and approval of trial proposals by an ethics committee. In the case of the CTN and CTX schemes, such a committee must have notified its existence to the Australian Health Ethics Committee of the National Health and Medical Research Council and provided assurances that it is operating within its guidelines. Ethics committees in Australia provide a combined ethical and scientific review process, which may be supplemented on an as-needed basis by external expert advice as the committee(s) concerned see fit.

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Question no: 5

Topic: Communication with the AMA

Type of Question: Hansard, page 13

Senator: Senator Reynolds

Question:

Senator REYNOLDS: Just on that point, can you either brief us now or tell us on notice exactly what communications you have had with the AMA federally and what their response has been on this issue?
If they have come back and said that what you have said is not correct, can you please provide that AMA advice to the committee?

Answer:

In 2013, 2014 and 2015 the department sent the Chief Medical Officer's (CMO) Lyme disease communique to the presidents of relevant medical colleges as well as to the President of the Australian Medical Association. On 8 March 2016, the CMO and departmental officials met with two secretariat staff from the AMA to discuss the latest evidence on the situation with Australia and Lyme disease.

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ANSWERS TO QUESTIONS ON NOTICE

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20 April 2016

Question no: 6

Topic: Communication with the AMA

Type of Question: Hansard, page 13

Senator: Senator Reynolds

Question:

Senator REYNOLDS: If you could take that on notice. It surprises me that you have never personally engaged with the AMA. If you check to make sure that the department has not had some form of advocacy or some more vigorous communication than an update.

Answer:

In 2013, 2014 and 2015 the department sent the Chief Medical Officer's (CMO) Lyme disease communique to the presidents of relevant medical colleges as well as to the President of the Australian Medical Association. On 8 March 2016, the CMO and departmental officials met with two secretariat staff from the AMA to discuss the latest evidence on the situation with Australia and Lyme disease.