DAP63

Automated measurement of ankle brachial pressure index for assessing the presence of peripheral arterial disease in people with leg ulceration

Addendum to the DAR

Produced by Aberdeen Health Technology Assessment Group

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REASON FOR ADDENDUM SUBMISSION

This addendum was prepared by the EAG in response to a request from the NICE technical team to provide additional scenario analyses prior to the first committee meeting. Additional scenarios in the addendum further explore the impact on cost-effectiveness of several different possible alternative time gains for automated tests (i.e., reductions in ulcer healing time) for venous ulcers with a true negative test result. Version 2.0 of the addendum provides further scenarios which replicate the time gain scenario analyses from version 1.0, but with removal of the costs of manual doppler testing. The EAG's view is that any modelled time gains may only be achievable in settings where there is limited access to manual doppler testing.

ADDITIONAL COST-EFFECTIVENESS RESULTS

Three additional scenario analyses are conducted on the "moderate" base case (Table 1) reporting the impact on results of true negative time gains of 6, 8, 12 and 16 weeks. Tables 2 and 3 provide threshold analyses (using NMB) illustrating the reductions in ulcer healing times for TN results that would be required before the tests would be considered cost-effective at threshold values of £20,000 and £30,000 per QALY respectively.

Tables 4,5 and 6 replicate the scenarios, removing the costs of manual doppler testing.

Table 1 Additional scenario analyses applied to the "moderate" set of base case assumptions

Test	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER (ranked)	ICER (vs. Manual)
Base case (moderate) - deterministic						
Manual Doppler	£11,961		8.032			--
BlueDop Vascular Expert	£12,099	£138	8.030	-0.002	Dominated	Dominated
WatchBP Office ABI	£12,276	£315	8.029	-0.003	Dominated	Dominated
WatchBP Office Vascular	£12,276	£315	8.029	-0.003	Dominated	Dominated
boso ABI-system 100	£12,392	£431	8.028	-0.005	Dominated	Dominated
MESI ABPI MD	£12,424	£463	8.027	-0.005	Dominated	Dominated
MESI mTABLET ABI	£12,427	£466	8.027	-0.005	Dominated	Dominated
Dopplex Ability	£12,501	£540	8.027	-0.006	Dominated	Dominated
Scenario A1 – Time gains for TN tests of 6 weeks (42 days)						
BlueDop Vascular Expert	£11,782	0	8.038	0.000		Dominant
WatchBP Office ABI	£11,929	£147	8.038	0.000	Dominated	Dominant
WatchBP Office Vascular	£11,930	£147	8.038	0.000	Dominated	Dominant
Manual Doppler	£11,961	£179	8.032	-0.006	Dominated	--
boso ABI-system 100	£12,053	£271	8.037	-0.001	Dominated	£20,045
MESI ABPI MD	£12,074	£292	8.037	-0.001	Dominated	£23,510
MESI mTABLET ABI	£12,077	£295	8.037	-0.001	Dominated	£24,042
Dopplex Ability	£12,153	£371	8.036	-0.002	Dominated	£45,662

Test	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER (ranked)	ICER (vs. Manual)
Scenario A2 – Time gains for TN tests of 8 weeks (56 days)						
BlueDop Vascular Expert	£11,677	£0	8.041	0.000		Dominant
WatchBP Office ABI	£11,814	£138	8.041	+0.000	£358,512	Dominant
WatchBP Office Vascular	£11,814	£0	8.041	-0.000	Dominated	Dominant
boso ABI-system 100	£11,941	£127	8.040	-0.001	Dominated	Dominant
MESI ABPI MD	£11,958	£144	8.040	-0.001	Dominated	Dominant
MESI mTABLET ABI	£11,961	£146	8.040	-0.001	Dominated	Dominant
Manual Doppler	£11,961	£147	8.032	-0.009	Dominated	--
Dopplex Ability	£12,037	£223	8.040	-0.001	Dominated	£10,253
Scenario A3 – Time gains for TN tests of 12 weeks (84 days)						
BlueDop Vascular Expert	£11,466	£0	8.046	0.000		Dominant
WatchBP Office ABI	£11,585	£119	8.047	0.001	£93,736	Dominant
WatchBP Office Vascular	£11,585	£0	8.047	0.000	Dominated	Dominant
boso ABI-system 100	£11,718	£133	8.046	-0.001	Dominated	Dominant
MESI ABPI MD	£11,727	£142	8.047	0.000	Dominated	Dominant
MESI mTABLET ABI	£11,730	£145	8.047	0.000	Dominated	Dominant
Dopplex Ability	£11,808	£223	8.046	-0.001	Dominated	Dominant
Manual Doppler	£11,961	£376	8.032	-0.015	Dominated	

Test	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER (ranked)	ICER (vs. Manual)
Scenario A4 – Time gains for TN tests of 16 weeks (112 days)						
BlueDop Vascular Expert	£11,255		8.051			Dominant
WatchBP Office ABI	£11,357	£102	8.053	0.002	£46,934	Dominant
WatchBP Office Vascular	£11,357	£0	8.053	0.000	Dominated	Dominant
boso ABI-system 100	£11,495	£139	8.052	-0.001	Dominated	Dominant
MESI ABPI MD	£11,498	£141	8.053	0.000	Dominated	Dominant
MESI mTABLET ABI	£11,500	£144	8.053	0.000	Dominated	Dominant
Dopplex Ability	£11,580	£224	8.053	0.000	Dominated	Dominant
Manual Doppler	£11,961	£605	8.032	-0.021	Dominated	

Abbreviations: ICER: Incremental cost-effectiveness ratio; QALY: Quality adjusted life years; TN: True negative.

Table 2: NMB at a threshold of £20,000 per QALY.

Time gain (automated, days)	Net Monetary Benefits							
	BlueDop Vascular Expert	Dopplex Ability	MESI ABPI MD	MESI mTABLET ABI	Manual Doppler	WatchBP Office ABI	WatchBP Office Vascular	boso ABI-system 100
0	£148,509	£148,033	£148,125	£148,123	**£148,684**	£148,305	£148,304	£148,162
7	£148,588	£148,124	£148,216	£148,213	**£148,684**	£148,392	£148,392	£148,249
14	£148,666	£148,214	£148,306	£148,303	**£148,684**	£148,480	£148,480	£148,336
21	**£148,745**	£148,305	£148,396	£148,394	£148,684	£148,568	£148,568	£148,423
28	**£148,823**	£148,395	£148,487	£148,484	£148,684	£148,656	£148,656	£148,510
35	**£148,901**	£148,486	£148,577	£148,574	£148,684	£148,744	£148,744	£148,597
42	**£148,980**	£148,576	£148,667	£148,664	£148,684	£148,831	£148,831	£148,684
49	**£149,058**	£148,666	£148,757	£148,754	£148,684	£148,919	£148,919	£148,770
56	**£149,137**	£148,756	£148,847	£148,844	£148,684	£149,007	£149,006	£148,857
63	**£149,215**	£148,846	£148,937	£148,934	£148,684	£149,094	£149,094	£148,943
70	**£149,293**	£148,936	£149,026	£149,024	£148,684	£149,181	£149,181	£149,030
77	**£149,372**	£149,026	£149,116	£149,114	£148,684	£149,269	£149,269	£149,116
84	**£149,450**	£149,116	£149,206	£149,203	£148,684	£149,356	£149,356	£149,202
91	**£149,528**	£149,206	£149,295	£149,293	£148,684	£149,444	£149,444	£149,289
98	**£149,607**	£149,295	£149,385	£149,382	£148,684	£149,531	£149,531	£149,375
105	**£149,685**	£149,385	£149,474	£149,472	£148,684	£149,618	£149,618	£149,461
112	**£149,763**	£149,474	£149,563	£149,561	£148,684	£149,705	£149,705	£149,547

Notes: Green (red) highlighted cells indicate the reductions in ulcer healing time for a TN test result that would be required to generate a NMB for automated tests that is greater than (lower than) the NMB for manual doppler testing at a WTP threshold of £20,000 per QALY.

Bold indicates the test strategy with the maximum NMB for each time gain scenario.

Table 3: NMB at £30,000 per QALY

Net Monetary Benefits

Time gain (automated, days)	BlueDop Vascular Expert	Dopplex Ability	MESI ABPI MD	MESI mTABLET ABI	Manual Doppler	WatchBP Office ABI	WatchBP Office Vascular	boso ABI-system 100
0	£228,813	£228,299	£228,400	£228,397	**£229,006**	£228,595	£228,595	£228,439
7	£228,904	£228,407	£228,506	£228,504	**£229,006**	£228,698	£228,698	£228,541
14	£228,996	£228,514	£228,613	£228,610	**£229,006**	£228,801	£228,801	£228,644
21	**£229,087**	£228,620	£228,719	£228,716	£229,006	£228,903	£228,903	£228,746
28	**£229,178**	£228,727	£228,825	£228,823	£229,006	£229,006	£229,006	£228,848
35	**£229,270**	£228,834	£228,931	£228,929	£229,006	£229,109	£229,109	£228,950
42	**£229,361**	£228,940	£229,037	£229,035	£229,006	£229,212	£229,212	£229,052
49	**£229,452**	£229,047	£229,143	£229,141	£229,006	£229,314	£229,314	£229,154
56	**£229,543**	£229,153	£229,249	£229,247	£229,006	£229,417	£229,417	£229,256
63	**£229,635**	£229,260	£229,355	£229,353	£229,006	£229,520	£229,520	£229,358
70	**£229,726**	£229,366	£229,461	£229,458	£229,006	£229,622	£229,622	£229,459
77	**£229,817**	£229,472	£229,567	£229,564	£229,006	£229,725	£229,724	£229,561
84	**£229,908**	£229,578	£229,672	£229,670	£229,006	£229,827	£229,827	£229,662
91	**£229,999**	£229,684	£229,778	£229,775	£229,006	£229,929	£229,929	£229,764
98	**£230,090**	£229,790	£229,883	£229,881	£229,006	£230,032	£230,032	£229,865
105	**£230,181**	£229,896	£229,989	£229,986	£229,006	£230,134	£230,134	£229,967
112	**£230,273**	£230,001	£230,094	£230,091	£229,006	£230,236	£230,236	£230,068

Notes: Green (red) highlighted cells indicate the reductions in ulcer healing time for a TN test result that would be required to generate a NMB for automated tests that is greater than (lower than) the NMB for manual doppler testing at a WTP threshold of £30,000 per QALY.

Bold indicates the test strategy with the maximum NMB for each time gain scenario.

Table 4 Additional scenario analyses applied to the "moderate" set of base case assumptions (removing the costs of manual doppler testing)

Test	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER (ranked)	ICER (vs. Manual)
Base case (moderate) - deterministic						
Manual Doppler	£11,961		8.032			--
BlueDop Vascular Expert	£12,099	£138	8.030	-0.002	Dominated	Dominated
WatchBP Office ABI	£12,276	£315	8.029	-0.003	Dominated	Dominated
WatchBP Office Vascular	£12,276	£315	8.029	-0.003	Dominated	Dominated
boso ABI-system 100	£12,392	£431	8.028	-0.005	Dominated	Dominated
MESI ABPI MD	£12,424	£463	8.027	-0.005	Dominated	Dominated
MESI mTABLET ABI	£12,427	£466	8.027	-0.005	Dominated	Dominated
Dopplex Ability	£12,501	£540	8.027	-0.006	Dominated	Dominated
Scenario A1 – Time gains for TN tests of 6 weeks (42 days)						
BlueDop Vascular Expert	£11,782		8.038	0.000		Dominant
WatchBP Office ABI	£11,929	£147	8.038	0.000	Dominated	Dominant
WatchBP Office Vascular	£11,930	£147	8.038	0.000	Dominated	Dominant
Manual Doppler	£11,941	£158	8.032	-0.006	Dominated	--
boso ABI-system 100	£12,053	£271	8.037	-0.001	Dominated	£24,492
MESI ABPI MD	£12,074	£292	8.037	-0.001	Dominated	£27,764

Test	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER (ranked)	ICER (vs. Manual)
MESI mTABLET ABI	£12,077	£295	8.037	-0.001	Dominated	£28,296
Dopplex Ability	£12,153	£371	8.036	-0.002	Dominated	£50,541
Scenario A2 – Time gains for TN tests of 8 weeks (56 days)						
BlueDop Vascular Expert	£11,677	£0	8.041	0.000		Dominant
WatchBP Office ABI	£11,814	£138	8.041	0.000	£358,512	Dominant
WatchBP Office Vascular	£11,814	£0	8.041	0.000	Dominated	Dominant
Manual Doppler	£11,941	£126	8.032	-0.009	Dominated	--
boso ABI-system 100	£11,941	£127	8.040	-0.001	Dominated	£82
MESI ABPI MD	£11,958	£144	8.040	-0.001	Dominated	£2,205
MESI mTABLET ABI	£11,961	£146	8.040	-0.001	Dominated	£2,525
Dopplex Ability	£12,037	£223	8.040	-0.001	Dominated	£13,001
Scenario A3 – Time gains for TN tests of 12 weeks (84 days)						
BlueDop Vascular Expert	£11,466	£0	8.046	0.000		Dominant
WatchBP Office ABI	£11,585	£119	8.047	0.001	£93,736	Dominant
WatchBP Office Vascular	£11,585	£0	8.047	0.000	Dominated	Dominant
boso ABI-system 100	£11,718	£133	8.046	-0.001	Dominated	Dominant
MESI ABPI MD	£11,727	£142	8.047	-0.000	Dominated	Dominant
MESI mTABLET ABI	£11,730	£145	8.047	-0.000	Dominated	Dominant

Test	Total cost	Incremental cost	Total QALY	Incremental QALY	ICER (ranked)	ICER (vs. Manual)
Dopplex Ability	£11,808	£223	8.046	-0.001	Dominated	Dominant
Manual Doppler	£11,941	£356	8.032	-0.015	Dominated	
Scenario A4 – Time gains for TN tests of 16 weeks (112 days)						
BlueDop Vascular Expert	£11,255		8.051			Dominant
WatchBP Office ABI	£11,357	£102	8.053	0.002	£46,934	Dominant
WatchBP Office Vascular	£11,357	£0	8.053	0.000	Dominated	Dominant
boso ABI-system 100	£11,495	£139	8.052	-0.001	Dominated	Dominant
MESI ABPI MD	£11,498	£141	8.053	0.000	Dominated	Dominant
MESI mTABLET ABI	£11,500	£144	8.053	0.000	Dominated	Dominant
Dopplex Ability	£11,580	£224	8.053	0.000	Dominated	Dominant
Manual Doppler	£11,941	£584	8.032	-0.021	Dominated	

Abbreviations: ICER: Incremental cost-effectiveness ratio; QALY: Quality adjusted life years; TN: True negative.

Table 5: NMB at a threshold of £20,000 per QALY (removing the costs of manual doppler testing).

Net Monetary Benefits

Time gain (automated, days)	BlueDop Vascular Expert	Dopplex Ability	MESI ABPI MD	MESI mTABLET ABI	Manual Doppler	WatchBP Office ABI	WatchBP Office Vascular	boso ABI-system 100
0	£148,509	£148,033	£148,125	£148,123	£148,704	£148,305	£148,304	£148,162
7	£148,588	£148,124	£148,216	£148,213	£148,704	£148,392	£148,392	£148,249
14	£148,666	£148,214	£148,306	£148,303	£148,704	£148,480	£148,480	£148,336
21	**£148,745**	£148,305	£148,396	£148,394	£148,704	£148,568	£148,568	£148,423
28	**£148,823**	£148,395	£148,487	£148,484	£148,704	£148,656	£148,656	£148,510
35	**£148,901**	£148,486	£148,577	£148,574	£148,704	£148,744	£148,744	£148,597
42	**£148,980**	£148,576	£148,667	£148,664	£148,704	£148,831	£148,831	£148,684
49	**£149,058**	£148,666	£148,757	£148,754	£148,704	£148,919	£148,919	£148,770
56	**£149,137**	£148,756	£148,847	£148,844	£148,704	£149,007	£149,006	£148,857
63	**£149,215**	£148,846	£148,937	£148,934	£148,704	£149,094	£149,094	£148,943
70	**£149,293**	£148,936	£149,026	£149,024	£148,704	£149,181	£149,181	£149,030
77	**£149,372**	£149,026	£149,116	£149,114	£148,704	£149,269	£149,269	£149,116
84	**£149,450**	£149,116	£149,206	£149,203	£148,704	£149,356	£149,356	£149,202
91	**£149,528**	£149,206	£149,295	£149,293	£148,704	£149,444	£149,444	£149,289
98	**£149,607**	£149,295	£149,385	£149,382	£148,704	£149,531	£149,531	£149,375
105	**£149,685**	£149,385	£149,474	£149,472	£148,704	£149,618	£149,618	£149,461
112	**£149,763**	£149,474	£149,563	£149,561	£148,704	£149,705	£149,705	£149,547

Notes: Green (red) highlighted cells indicate the reductions in ulcer healing time for a TN test result that would be required to generate a NMB for automated tests that is greater than (lower than) the NMB for manual doppler testing at a WTP threshold of £20,000 per QALY.

Bold indicates the test strategy with the maximum NMB for each time gain scenario.

Table 6: NMB at £30,000 per QALY (removing the costs of manual doppler testing)

Net Monetary Benefits

Time gain (automated, days)	BlueDop Vascular Expert	Dopplex Ability	MESI ABPI MD	MESI mTABLET ABI	Manual Doppler	WatchBP Office ABI	WatchBP Office Vascular	boso ABI-system 100
0	£228,813	£228,299	£228,400	£228,397	£229,027	£228,595	£228,595	£228,439
7	£228,904	£228,407	£228,506	£228,504	£229,027	£228,698	£228,698	£228,541
14	£228,996	£228,514	£228,613	£228,610	£229,027	£228,801	£228,801	£228,644
21	**£229,087**	£228,620	£228,719	£228,716	£229,027	£228,903	£228,903	£228,746
28	**£229,178**	£228,727	£228,825	£228,823	£229,027	£229,006	£229,006	£228,848
35	**£229,270**	£228,834	£228,931	£228,929	£229,027	£229,109	£229,109	£228,950
42	**£229,361**	£228,940	£229,037	£229,035	£229,027	£229,212	£229,212	£229,052
49	**£229,452**	£229,047	£229,143	£229,141	£229,027	£229,314	£229,314	£229,154
56	**£229,543**	£229,153	£229,249	£229,247	£229,027	£229,417	£229,417	£229,256
63	**£229,635**	£229,260	£229,355	£229,353	£229,027	£229,520	£229,520	£229,358
70	**£229,726**	£229,366	£229,461	£229,458	£229,027	£229,622	£229,622	£229,459
77	**£229,817**	£229,472	£229,567	£229,564	£229,027	£229,725	£229,724	£229,561
84	**£229,908**	£229,578	£229,672	£229,670	£229,027	£229,827	£229,827	£229,662
91	**£229,999**	£229,684	£229,778	£229,775	£229,027	£229,929	£229,929	£229,764
98	**£230,090**	£229,790	£229,883	£229,881	£229,027	£230,032	£230,032	£229,865
105	**£230,181**	£229,896	£229,989	£229,986	£229,027	£230,134	£230,134	£229,967
112	**£230,273**	£230,001	£230,094	£230,091	£229,027	£230,236	£230,236	£230,068

Notes: Green (red) highlighted cells indicate the reductions in ulcer healing time for a TN test result that would be required to generate a NMB for automated tests that is greater than (lower than) the NMB for manual doppler testing at a WTP threshold of £30,000 per QALY.

Bold indicates the test strategy with the maximum NMB for each time gain scenario.

INTERPRETATION

The additional analyses in this addendum illustrate that there may be potential for automated tests to be a cost-effective use of resource if it was possible to achieve reductions in ulcer healing time for venous ulcers in the presence of a true negative test result. Such reductions in ulcer healing time could only plausibly be achieved in settings where there is limited access to, or required skills among healthcare professionals to complete, manual doppler testing. The threshold value of reduction in venous ulcer healing time that would need to be achieved before an automated test might be considered cost-effective ranges from 3 to 7 weeks across the different automated test strategies. Tests with higher sensitivity (i.e., fewer false negative test results) would likely require a lower reduction in venous ulcer healing time to offset the additional risks of FN test results. Removing the costs of manual testing from these scenarios has minimal impact on results (only to increase the threshold value of time gains slightly for WATCH BP (and only then at the £30,000 threshold – see Table 7 compared to Table 3).

Despite the potential for cost-effectiveness in a limited setting demonstrated in the threshold analyses presented here, these results should be interpreted cautiously, and considered together with the other uncertainties described in the DAR. In particular, the threshold (minimum) reduction in venous ulcer healing time that would be required before a test could be considered cost-effective will depend on the true diagnostic accuracy of the test, the underlying prevalence of arterial disease, and assumptions about whether or not inaccurate test results (FN and FP) are acted on in clinical practice. For example, the moderate base case analysis on which these scenarios are based assumes that a FN test result in a patient with purely arterial disease would not be acted upon (i.e., it is assumed that a holistic patient assessment would mean that strong compression would not be applied to the arterial ulcer). However, in more pessimistic scenarios, where all FN results are acted upon (both arterial and mixed ulcers) the threshold value of reduction in venous ulcer healing time would need to increase further before the automated tests could be considered cost-effective.

The EAG is of the view that these additional assumptions, together with uncertainty surrounding the underlying diagnostic accuracy in a population of leg ulcer patients mean that the threshold value of reductions in venous ulcer healing time that an automated test would need to achieve before being cost-effective is highly uncertain.