Timeframes for Common Drug Review Procedure

	Task within Review Process	Timeframe (in Business Days)	Weeks
Administrative Tasks*			
1	Submission deemed complete	5	1
	Resubmission deemed complete	10	2
2	Manufacturer's binders received by CDR	5	1
3	Manufacturer's binders received by CDR Reviewers	3	0.6
Review Process			
4	CDR Reviewers' Reports completed • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmacoeconomic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer	45	9
5	Comments from Manufacturer on Reviewers' Reports received by CDR	7	1.5
6	Reviewers' Reply to Manufacturer's comments completed	7	1.5
7	CEDAC Brief completed and sent to CEDAC Members and Participating Drug Plans	5	1
8	CEDAC meeting (placement on CEDAC agenda)	10 to 40	2 to 8
9	CEDAC Recommendation and Reasons for Recommendation sent to Drug Plans, ACP and Manufacturer; Final CDR Reviews sent to Manufacturer for information	5	l
10	Embargo Period† Manufacturers may make Request for Reconsideration, and Drug Plans may make Request for Clarification of Recommendation and Reasons for Recommendation	10	2
11 (a)	Final Recommendation sent to Drug Plans, ACP, and Manufacturer (no Requests for Clarification AND no Request for Reconsideration; or Request for Reconsideration resolved)	5	1
OR			
11 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification requested, no Request for Reconsideration)	5	1
	Total Review Time for Submissions*	**94 to 124 days**	**19 to 25 weeks**
	Total Review Time for Resubmissions*	**94 to 124 days**	**19 to 25 weeks**
OR			
11 (c)	Placed on CEDAC agenda for Reconsideration (at Manufacturer's request)	25 Depends on Meeting Dates	5
12	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	1

*Administrative Time is not included in the calculations of the Total Review Times

†The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the Notice of Final Recommendation