TITLE	**COMPARATIVE EFFECTIVENESS AND SAFETY OF BUDESONIDE STERINEBS® VS. PULMICORT RESPULES® IN A US POPULATION OF ASTHMA PATIENTS.**
Subtitle	Historic cohort, US database study comparing effectiveness and safety of nebulised medication labelled by TEVA Ltd (Budesonide SteriNebs®) against the originator product (Pulmicort Respules®), in patients with a diagnosis for asthma.
Protocol version identifier	v04
Active substance	Budesonide
Medicinal product	Budesonide SteriNebs® 0.25 mg/0.50 mg
National Drug Code (NDC)	0093-6815-73 (0.25 mg) 0093-6816-73 (0.50 mg)
Marketing authorization holder	Arrow Generics Ltd InsideView Technologies, Inc. 444 De Haro Street, Suite 210 San Francisco, CA 94107 USA
Marketing category and application number	ANDA-077519
Research questions and objectives	To examine if nebulised medication labelled by TEVA Ltd (Budesonide SteriNebs®) is non-inferior (as effective and safety as) to the originator product (Pulmicort Respules®).
Country of study	US
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1. BACKGROUND AND RATIONALE

Teva Ltd is a global company ranking among the 10 top pharmaceutical companies in the world. Headquartered in Israel, Teva is active in 60 countries, with over 46,400 dedicated employees worldwide. The company is now looking to launch 3 different nebuliser products in China where the market is rapidly expanding: Budesonide SteriNebs®, Salbutamol SteriNebs® and Ipratropium Bromide/Albuterol SteriNebs®. This protocol focuses on Budesonide SteriNebs®.

Budesonide SteriNebs® is an inhalation suspension containing Budesonide, an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity. It is used for long-term maintenance therapy to control and prevent asthma symptoms and as prophylactic therapy in children 12 months to 8 years of age.

In 2008, Budesonide SteriNebs® has been approved by the US Food and Drug Administration and in December 2009 was launched on the market as generic product of Pulmicort Respules®, which is marketed worldwide, including China.

In order to support a clinical trial waiver for marketing Budesonide SteriNebs® in China, Teva will provide recent data demonstrating their product is not inferior to the originator. To accomplish this, an observational data-base study will be conducted comparing effectiveness and safety of the long-term usage of the two products in a US asthma population. A regulatory standard protocol, together with the completed analysis will be produced for the submission to Chinese regulators.

2. AIM AND OBJECTIVES

The aim of this study is to compare Budesonide SteriNebs® with its originator, Pulmicort Respules®. The primary objective is to assess whether effectiveness (in terms of exacerbations) of Budesonide SteriNebs® is non-inferior to that of Pulmicort Respules® in both adult and children diagnosed with asthma. The secondary objective is to compare safety of Budesonide SteriNebs® with Pulmicort Respules® in both adults and children diagnosed with asthma.

3. DATA SOURCE AND EXTRACTION

This study will use the Clinformatics™ Data Mart (CDM) database[1], an anonymous patient longitudinal database (APLD, US observational data), which contains retrospective claims data (2000-2012) from an employed, commercially insured United States population, including more than 45 million unique members. It is provided by OptumInsight Life Sciences[2] and contains:

- Medical claims (primary care and secondary care)
- Pharmacy claims
- Laboratory results
- Pricing information

Data from this database will be obtained for the final analysis using an appropriate data-extraction algorithm. Obtained data will be then validated ad cleaned for further statistical analysis.

4. RESEARCH METHODS

4.1 Study products

- Reference Therapy: PULMICORT RESPULES®

Originator product consisting of a suspension for inhalation via jet nebuliser containing the corticosteroid budesonide. Three dose strengths are available in single-dose ampules (Respules™ ampules): 0.25 mg; 0.50 mg and 1 mg per 2 mL.

- Investigational Product: BUDESONIDE STERINEBS®

Generic product of Pulmicort Respules®. It is a suspension for inhalation via jet nebuliser containing the corticosteroid budesonide and is available in two dose strengths: 0.25 mg and 0.50 mg per 2 mL.

4.2 Study period

The date of first launch of Budesonide SteriNebs® in US is December 2009. In order to include as many patients as possible, the study period will cover 2 years within a maximum period

[1] www.optum.com
[2] www.optuminsight.com

from November 2008 (1 year before drug launch) until last available data on the CDM database (September 2012).

4.3 Study design

This study is a two-year matched historic cohort, database study consisting of one-year baseline period, an index prescription date (IPD) and a one-year outcome period.

The baseline period is intended for patient characterization and confounder definition and is the one-year prior to IPD. **The IPD** is defined as the date (day/month/year) at which:

(1) CHANGE SUB-COHORT: asthma patients who were on Pulmicort Respules® in baseline changed to Budesonide SteriNebs® (patients receive ≥ 1 prescription) [3].

(2) CONTINUING SUB-COHORT: asthma patients who were on Pulmicort Respules® in baseline received ≥1 continued prescription for Pulmicort Respules®.

(3) INITIATION SUB-COHORTS: asthma patients who were not on ICS nebulisers in baseline initiated on either Pulmicort Respules® or Budesonide SteriNebs®.

Change and initiation sub-cohorts for Budesonide SteriNebs® will be combined to form the "Budesonide SteriNebs® treatment group" and compared to "Pulmicort Respules® treatment group" consisting of a combination of continuing and initiation sub-cohorts for Pulmicort Respules®. Matching will be performed between the two initiation sub-cohorts and between the change and continuing sub-cohorts to ensure comparison of homogeneous groups of patients. A sub-analysis comparing the two initiation sub-cohorts only will also be performed as a sensitivity analysis to confirm the main results. Effectiveness outcomes over the one-year outcome period following IPD will be compared between the treatments.

The outcome period is one-year period following IPD and will be used to compare effectiveness and safety of Budesonide SteriNebs® versus Pulmicort Respules®. One-year time period is deemed necessary to record any measurable change in outcomes such as hospitalisations, and also to allow for seasonal changes in respiratory disease and its related conditions.

[3] These patients may later change to Budesonide SteriNebs® after the one year outcome period. This may allow for same patients to be included in both cohorts. We will ensure that these patients will not be used as their own control and will not be matched during statistical analysis.

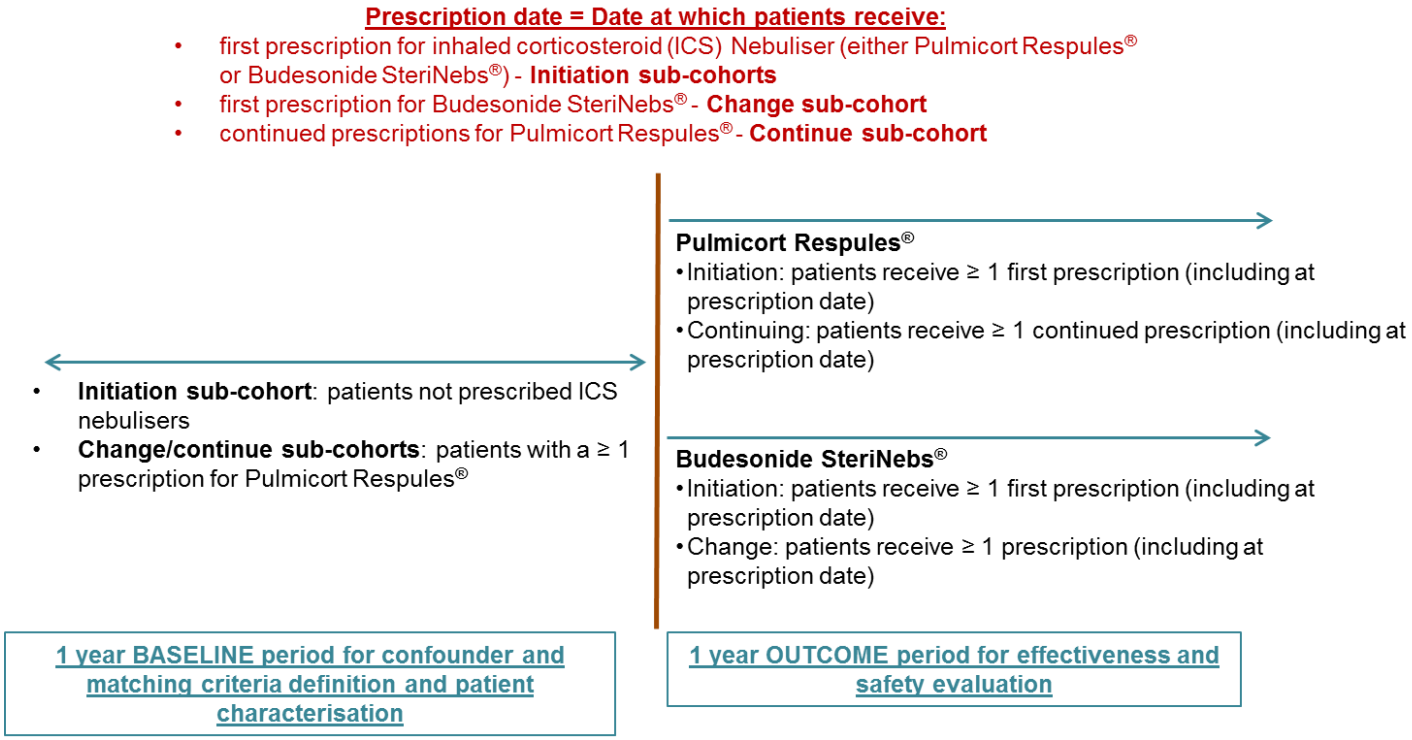

Figure 1: Study design

4.4 Study population

People who have been diagnosed with asthma and have been prescribed Pulmicort Respules® will be included in the analysis. Patients must meet the following criteria:

Inclusion criteria:

- Aged 1-80 years

  Adult population: 12-80 years

  Paediatric population: ≥1 and <12 years

- Diagnosis for asthma (at any time), based on ICD9 codes (Annex 1)
- Change sub-cohort: ≥1 prescription for Pulmicort Respules® in baseline (1 year prior to IPD) and ≥1 prescriptions for Budesonide SteriNebs® at IPD
- Continuing sub-cohort: ≥1 prescription for Pulmicort Respules® during baseline (1 year prior to IPD) and ≥1 continued prescription for Pulmicort Respules® at IPD
- Initiation sub-cohorts: no prescriptions for ICS nebulisers in baseline (1 year prior to IPD) and ≥1 prescription for either Budesonide SteriNebs® or Pulmicort Respules® at IPD

Exclusion criteria:

- Any other chronic respiratory disease other than asthma
- Use of other ICS nebulisers besides Pulmicort Respules® or Budesonide SteriNebs® in the baseline (1 year prior to IPD).

5. VARIABLES

5.1 Primary outcome

Primary outcome of this study is "effectiveness", evaluated in terms of:

- Asthma-related[4] hospitalisation rate (number of hospitalisations in the outcome year)
- Severe exacerbation rate (number of American Thoracic Society (ATS)/European Respiratory Society (ERS) exacerbations in the outcome year)

Whereby:

Asthma-related hospitalisation is defined as:

- Asthma-related emergency department (ED) visits OR
- Asthma-related Inpatient admissions

Severe exacerbation is defined as[5] (ATS/ERS definition):

- Asthma-related hospitalisation (as defined above), OR
- Prescription for an acute course of oral steroids[6] from a lower respiratory event[7]

5.2 Secondary (exploratory) outcome

Secondary outcome of this study is "safety", evaluated in terms of Adverse Events (AEs).

[4] Asthma-related is defined as one of the diagnostic codes for asthma; or other non-chronic lower respiratory diseases; or lower respiratory tract infection (LRTI: pneumonia, influenza, bronchitis & bronchiolitis or other) as defined in appendix 1.

[5] When two exacerbations occur within two weeks from each other – they are considered as the same exacerbation and will only be counted once

[6] Acute oral steroid use will be defined as all courses where dosing instructions suggest exacerbation treatment (e.g. 6,5,4,3,2,1 reducing, or 30mg as directed) and/or all courses unlikely to be maintenance therapy, i.e. with no dosing instructions but recorded within a ±5-day window from a lower respiratory event (as defined in foot note 7)

[7] A lower respiratory event is either an asthma-related ED visit/ hospital admission/ ambulatory visit (as defined in foot note 4) or a respiratory investigation recorded within a ±5-day window from the prescription. A respiratory investigation comprises one of the following clinical procedure: chest radiograph (x-ray), chest computerised tomography (CT) scan, bronchogram, pneumogram, chest sonogram, lung biopsy and bronchoscopy (see appendix 2)

Unique AEs are not identified in the CDM database. Instead pre-defined adverse terms can be identified and coded according to the Medical Dictionary for Regulatory Activities (MedDRA) standards. These will include AE typical of ICS use and as specified in the summary of study product characteristics.

In order to do so, we will use ICD-9 Codes and convert them to MedDRA codes categorised by disease area (e.g. cardiovascular events, renal events).
Data will be extracted on all adverse events, serious or otherwise. Events of particular note include:

- Cardiac events
- Glaucoma
- Prostatic hypertrophy
- Respiratory adverse events
- Death (serious AE)

5.3 Demographics and baseline variables

In order to capture real-world data on the utilisation of Budesonide SteriNebs® and Pulmicort Respules® in clinical practice, the patients prescribed these therapies will be characterised according to their:

- Age at IPD and sex
- Prior asthma maintenance therapy (maintenance therapy prescribed before IPD)
- Co-morbidities (presence of co-morbid diagnoses, also using the Charlson Comorbidities Index)
- Baseline co-medication (presence of prescription for gastroesophageal reflux disease (GERD), (captured only with a diagnosis of GERD), acetaminophen (paracetamol) and antibiotics (abx)
- Ambulatory visits[8] (asthma-related visits, any visits)
- Number of asthma "clinical" exacerbations, defined as:
  - Severe ATS/ERS exacerbation (as defined above) OR
  - Course for antibiotics from a lower respiratory event[7]
- Disease control in the year prior to IPD, defined as:

[8]Ambulatory visits can either be primary care visits or outpatient department visit

Risk domain asthma control

Where control is defined as the absence of:

- Severe exacerbations AND
- Out-patient department attendances

Overall asthma control

Where control is defined as:

- Risk Domain Asthma control AND
- Average daily dose of ≤180mcg albuterol

6. STATISTICS

Analyses will be carried out using SPSS Statistics 21 (IBM SPSS Statistics, UK) and SAS 9.3 (SAS Institute, UK) software.

6.1 Power calculation

A previous study has reported that 26.1% of asthma patients (2,019 out of 7,734) using ICS have at least one exacerbation in the one-year period after initiation. Assuming the proportion in the standard group is 26.1% and the expected difference between the proportions is 0, a sample size of 2,172 in each group would be required to adequately power the study in a two-group large-sample normal approximation, with a one-sided 0.050 significance level. This would provide 90% power to reject the null hypothesis that the investigational and the reference are not equivalent, i.e. the difference in proportions is -3.9% (15% of 26.1%) or further from zero in the same direction.

Number of patients potentially available from the US database are reported below:

Study drugs	NDC codes	strength	Launch date	Patient Numbers
Budesonide SteriNebs® (Teva USA)	00093681573	0.25 mg/2mL	11-19-2008	**74,814**
	00093681673	0.5 mg/2mL	11-19-2008	
Pulmicort Respules® (AstraZeneca LP)	00186198804	0.25 mg/2mL	09/08/2000	**115,029**
	00186198904	0.5 mg/2mL	09/08/2000	
	00186199004	1 mg/2mL	09-17-2007	

6.2 Exploratory analysis

Prior to the extended statistical analysis, an exploratory analysis of each cohort will be carried out for data validation and to identify potential outliers. The exploratory analysis will also help to investigate possible baseline differences between the two cohorts in order to evaluate whether the analysis may benefit from matching. Unmatched/matched statistical analyses

will be performed using appropriate regression modelling. This robust statistical approach minimizes potential confounding of results by indication or severity. Statistically significant results will be defined as $p<0.05$ and trends as $p<0.10$.

6.3 Summary statistics

Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by treatment, including:

(1) Variables measured on the interval/ratio scale:

- Sample size (n) and percentage non-missing
- Mean and Variance / Standard Deviation
- Range (Minimum / Maximum)
- Median and Inter-quartile Range (25th and 75th percentiles)

(2) Categorical variables:

- Sample size (n)
- Range (if applicable)
- Count and Percentage by category (distribution)

6.4 Comparisons between treatment groups

Treatment groups will be compared using the following tests:

(1) Variables measured on the interval/ratio scale:

- t-test (normal distribution)
- Mann Whitney U-test (skewed data)

(2) Categorical variables:

- Chi square test

6.5 Patient matching

If necessary depending on baseline results, individual patients in the two treatment groups (i.e. Pulmicort Respules® or Budesonide SteriNebs®) will be matched to ensure the comparison of like patients. All the valid records satisfying inclusion and exclusion criteria in the Pulmicort Respules® study cohort are considered as potential 1:1 matches to Budesonide SteriNebs® patients. The final selection of matched patients will ensure that only unique patients are selected from all cohorts by random methods. Random selection process through SAS statistical software will be used to avoid selection bias. Patients initiating on Pulmicort Respules® will be matched with patients initiating on Budesonide SteriNebs® and patients in

the continuing cohort will be matched with patients in the change cohort. The matching criteria and matching ratio will be determined once the baseline data are examined. Baseline characterisation will be via demographics and clinical variables (for example age, gender, baseline exacerbations, acute oral steroid use or average daily SABA inhalers use during baseline). Any residual differences between the treatment groups after matching that are considered to be potentially significant ($p<0.10$) and any variables predictive of the outcome will be adjusted for through further statistical modelling. When variables are co-linear in nature, clinical input will be sought to decide which of those that are co-linear are put into the model.

6.6 Comparisons between effectiveness outcomes (primary analyses)

(1) Asthma-related hospitalisation rate

Hospitalisation in the outcome period will be compared between treatment groups using a Conditional Poisson regression model. The model will use empirical standard errors (for more conservative confidence interval estimations) and adjustments will be made for potential baseline confounders. The adjusted rate ratio with 95% confidence interval will be reported.

(2) Severe exacerbations rate

Exacerbations rates in the outcome period will be compared between treatment groups using a conditional Poisson regression model. The model will use empirical standard errors (for more conservative confidence interval estimations) and adjustments will be made for potential baseline confounders. The adjusted rate ratio with 95% confidence interval will be reported.

Baseline characterisation will be used to adjust for confounding factors. Those variables that will be significantly different or show a trend towards a difference ($p < 0.10$) between the treatment groups at baseline will be included as potential confounding factors. In addition, variables that are found to be predictive ($p < 0.05$) of the outcome through multivariate analysis will also be considered as potential confounders.

6.7 Comparisons among safety variables (secondary/exploratory analyses)

AEs rates (as total and individual events) in the outcome period will be compared between treatment groups using a conditional Poisson regression model. The model will use empirical standard errors (for more conservative confidence interval estimations), and adjustments will

be made for potential baseline confounders. The adjusted rate ratio with 95% confidence interval will be reported.

A more detailed description of the statistical analysis is reported in the attached statistical analysis plan (SAP).

7. LIMITATIONS OF RESEARCH METHODS

As with all database studies, a number of limitations exists for which it is not possible to adjust (e.g. potential confounding factors with the problem of internal validity).

The methods of adjustment described in the Study Design will be used to address all factors for which it is possible to account for. Given the inherent limitations of database studies, however, the study results need to be viewed in conjunction with those from other studies, in particular randomised controlled trials.

8. PROTECTION OF HUMAN SUBJECTS

Due to the sensitive nature of personal medical data, all the researchers involved in this study are aware of ethical and regulatory aspects and strive to take all reasonable measures to ensure compliance with ethical and regulatory issues on privacy. The CDM database used for this study is already used for Pharmacoepidemiological research[9] and has a well-developed mechanism to ensure that regulations dealing with ethical use of the data and adequate privacy control are adhered to.

9. REGULATORY AND ETHICAL COMPLIANCE

This study was designed and shall be implemented and reported in accordance with the criteria of the "European Network Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) study" and follows the ENCePP Code of Conduct (EMA 2014)[10].

10. DISSEMINATION PLAN

This study will be registered with ENCePP with the aim of presenting initial results in poster/oral format at appropriate thoracic conferences. At least one manuscript containing more detailed results and methodology will be submitted to a journal specialising in

[9] Tkacz J et al. Clin Ther. 2014; 36(5):737-47.
Oleen-Burkey M et al. BMC Neurol. 2014; 14;14:11.
Lin J et al. J Med Econ. 2013; 16(5):685-90.
Oleen-Burkey M et al. J Med Econ. 2013; 16(3):397-406.
[10] Revision 3 of the ENCePP Code of Conduct, available at: http://www.encepp.eu/code_of_conduct/.

respiratory medicine. Submission for publications should be made as soon as the analyses are completed and the results are verified. Preferred respiratory congresses and journals will be agreed in discussion with Teva Ltd.

11. STUDY TEAM

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Research in Real Life (RiRL)

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12. ANNEX 1

ICD-9 disease classification:

VARIABLE	CATEGORY	ICD-9 CODES				
BMI	Underweight • Adults: <19 kg/m^2 • Paeds: <5th percentile	78322	V850	V8551		
	Normal • Adults: 19- 24.9 kg/m^2 • Paeds: 5th -<85th percentile	V851	V8552			
	Overweight • Adults: 25-29.9 kg/m^2 • Paeds:8 5th -<95th percentile	27802	V8522	V8523	V8525	V8553
		V852	V8521	V8524		
	Obese • Adults: >=30 kg/m^2 • Paeds: >=95th percentile	27800	V8534	V8541	V8531	V8538
		27801	V8535	V8542	V8532	V8539
		V853	V8536	V8543	V8533	V854
		V8530	V8537	V8544	V8545	V8554
Asthma & COPD diagnosis	Asthma	49300	49311	49390	49310	49392
		49301	49312	49391	49381	49382
		49302	49310			
	Asthma + COPD	49320	49321	49322		
	COPD	490	49122	4940	49120	4928
		4910	4918	4941	49121	5181
		4911	4919	496	4920	5182
Other lower respiratory diseases	Chronic	01000	01191	01381	01611	01751
		01001	01192	01382	01612	01752
		01002	01193	01383	01613	01753
		01003	01194	01384	01614	01754
		01004	01195	01385	01615	01755
		01005	01196	01386	01616	01756
		01006	01200	01390	01620	01760
		01010	01201	01391	01621	01761
		01011	01202	01392	01622	01762
		01012	01203	01393	01623	01763
		01013	01204	01394	01624	01764
		01014	01205	01395	01625	01765
		01015	01206	01396	01626	01766
		01016	01210	01400	01630	01770
		01080	01211	01401	01631	01771
		01081	01212	01402	01632	01772
		01082	01213	01403	01633	01773
		01083	01214	01404	01634	01774
		01084	01215	01405	01635	01775
		01085	01216	01406	01636	01776
		01086	01220	01480	01640	01780
		01090	01221	01481	01641	01781
		01091	01222	01482	01642	01782
		01092	01223	01483	01643	01783
		01093	01224	01484	01644	01784
		01094	01225	01485	01645	01785
		01095	01226	01486	01646	01786
		01096	01230	01500	01650	01790
		01100	01231	01501	01651	01791

		01101	01232	01502	01652	01792
		01102	01233	01503	01653	01793
		01103	01234	01504	01654	01794
		01104	01235	01505	01655	01795
		01105	01236	01506	01656	01796
		01106	01280	01510	01660	01800
		01110	01281	01511	01661	01801
		01111	01282	01512	01662	01802
		01112	01283	01513	01663	01803
		01113	01284	01514	01664	01804
		01114	01285	01515	01665	01805
		01115	01286	01516	01666	01806
		01116	01300	01520	01670	01880
		01120	01301	01521	01671	01881
		01121	01302	01522	01672	01882
		01122	01303	01523	01673	01883
		01123	01304	01524	01674	01884
		01124	01305	01525	01675	01885
		01125	01306	01526	01676	01886
		01126	01310	01550	01690	01890
		01130	01311	01551	01691	01891
		01131	01312	01552	01692	01892
		01132	01313	01553	01693	01893
		01133	01314	01554	01694	01894
		01134	01315	01555	01695	01895
		01135	01316	01556	01696	01896
		01136	01320	01560	01700	5110
		01140	01321	01561	01701	5111
		01141	01322	01562	01702	4950
		01142	01323	01563	01703	4951
		01143	01324	01564	01704	4952
		01144	01325	01565	01705	4953
		01145	01326	01566	01706	4954
		01146	01330	01570	01710	4955
		01150	01331	01571	01711	4956
		01151	01332	01572	01712	4957
		01152	01333	01573	01713	4958
		01153	01334	01574	01714	4959
		01154	01335	01575	01715	4760
		01155	01336	01576	01716	4761
		01156	01340	01580	01720	500
		01160	01341	01581	01721	501
		01161	01342	01582	01722	502
		01162	01343	01583	01723	503
		01163	01344	01584	01724	504
		01164	01345	01585	01725	505
		01165	01346	01586	01726	5061
		01166	01350	01590	01730	5062
		01170	01351	01591	01731	5063
		01171	01352	01592	01732	5064
		01172	01353	01593	01733	5069
		01173	01354	01594	01734	5070
		01174	01355	01595	01735	5071
		01175	01356	01596	01736	5078
		01176	01360	01600	01740	5080

		01180	01361	01601	01741	5081
		01181	01362	01602	01742	5082
		01182	01363	01603	01743	5088
		01183	01364	01604	01744	5089
		01184	01365	01605	01745	515
		01185	01366	01606	01746	51282
		01186	01380	01610	01750	51283
		01190	5172	5178	51883	51884
	Non-chronic	5100	51633	5185	5160	5193
		5109	51634	51851	5161	5194
		5130	51635	51852	5162	5198
		5131	51636	51853	5163	51902
		5120	51637	5186	51630	51909
		5121	5164	5187	51631	51911
		5122	5165	51881	51632	51919
		5128	51661	51882	5199	5171
		51281	51662	51889	51669	5180
		51284	51663	51900	5168	5183
		51289	51664	51901	5169	5184
Lower respiratory tract infections (LRTIs)	pneumonia	0330	4821	48284	4803	48242
		0331	4822	48289	4808	48249
		0338	48230	4829	4809	48281
		0339	48231	4830	481	48282
		0415	48232	4831	4820	48283
		4800	48239	4838	486	4847
		4801	48240	4841	4845	4848
		4802	48241	4843	4846	485
	Influenza	4870	48801	48812	488	4881
		4871	48802	48819	4880	48811
		4878	48809	48881	48882	48889
	Bronchitis &Bronchiolitis	4660	46611	46619	5060	
	Other LRTIs	1363	5119	78609	46421	78604
		3061	78600	7862	5118	78605
		46400	78601	7863	51181	78606
		46401	78602	78630	51189	78607
		46420	78603	78631	79539	78639
		7864	7867	7869		

13. ANNEX 2

Procedure codes for respiratory investigation

PROCEDURE	CODE	TYPE OF CODE
CHEST X-RAY	71010	CPT-4
CHEST X-RAY	71015	CPT-4
CHEST X-RAY	71020	CPT-4
CHEST X-RAY	71021	CPT-4
CHEST X-RAY	71022	CPT-4
CHEST X-RAY AND FLUOROSCOPY	71023	CPT-4
CHEST X-RAY	71030	CPT-4
CHEST X-RAY AND FLUOROSCOPY	71034	CPT-4
CHEST X-RAY	71035	CPT-4
CONTRAST X-RAY OF BRONCHI	71040	CPT-4
CONTRAST X-RAY OF BRONCHI	71060	CPT-4
X-RAY EXAM OF RIBS/CHEST	71101	CPT-4
X-RAY EXAM OF RIBS/CHEST	71111	CPT-4
MRI CHEST W/O DYE	71550	CPT-4
MRI CHEST W/DYE	71551	CPT-4
MRI CHEST W/O & W/DYE	71552	CPT-4
MRI ANGIO CHEST W OR W/O DYE	71555	CPT-4
PLAIN RADIOGRAPHY / THORACIC AORTA	B300	ICD10
PLAIN RADIOGRAPHY OF THORACIC AORTA	B300ZZZ	ICD10
PLAIN RADIOGRAPHY RESPIRATORY SYS	BB0	ICD10
PLAIN RADIOGRAPHY / UPPER AIRWAYS	BB0D	ICD10
PLAIN RADIOGRAPHY OF UPPER AIRWAYS	BB0DZZZ	ICD10
PLAIN RADIOGRAPHY / THORACIC DISCS	BR02	ICD10
PLAIN RADIOGRAPHY OF THORACIC DISCS	BR02ZZZ	ICD10
PLAIN RADIOGRAPHY / THORACIC SPINE	BR07	ICD10
PLAIN RADIOGRAPHY OF THORACIC SPINE	BR07ZZZ	ICD10
PLAIN RADIOGRAPHY / CHEST	BW03	ICD10
PLAIN RADIOGRAPHY OF CHEST	BW03ZZZ	ICD10
CT THORAX W/O DYE	71250	CPT-4
CT THORAX W/DYE	71260	CPT-4
CT THORAX W/O & W/DYE	71270	CPT-4
CT ANGIOGRAPHY, CHEST	71275	CPT-4
CT CHEST SPINE W/O DYE	72128	CPT-4
CT CHEST SPINE W/DYE	72129	CPT-4
CT CHEST SPINE W/O & W/DYE	72130	CPT-4
CT CT SCAN/THORACIC AORTA	B320	ICD10
CT SCAN THOR AORTA HI OSMLR CONTRST	B3200ZZ	ICD10
CT CT SCAN THOR AORTA OTH CONTRST	B320YZZ	ICD10
CT SCAN THORACIC AORTA IV OPT COH	B320Z2Z	ICD10
CT CT SCAN OF THORACIC AORTA	B320ZZZ	ICD10

CT CT SCAN/TRACHEA/AIRWAYS	BB2F	ICD10
CT TR/AIRWAYS HI OSM CONT UN/ENHNCD	BB2F00Z	ICD10
CT SCAN TR/AIRWAYS HI OSMLR CONTRST	BB2F0ZZ	ICD10
CT TR/AIRWAYS L OSM CONT UN/ENHNCD	BB2F10Z	ICD10
CT SCAN TR/AIRWAYS L OSMLR CONTRST	BB2F1ZZ	ICD10
CT TRACH/AIRWAYS OTH CONT UN/ENHNCD	BB2FY0Z	ICD10
CT CT SCAN TR/AIRWAYS OTH CONTRST	BB2FYZZ	ICD10
CT CT SCAN OF TRACHEA/AIRWAYS	BB2FZZZ	ICD10
CT CT SCAN/THORAX	BP2W	ICD10
CT CT SCAN THOR HI OSMOLAR CONTRST	BP2W0ZZ	ICD10
CT CT SCAN THOR LOW OSMOLAR CONTRST	BP2W1ZZ	ICD10
CT CT SCAN THORAX OTHER CONTRAST	BP2WYZZ	ICD10
CT CT SCAN/THORACIC SPINE	BR27	ICD10
CT CT SCAN OF THORACIC SPINE	BR27ZZZ	ICD10
CT CT SCAN/CHEST & ABDOMEN	BW24	ICD10
CT CT SCAN CHEST ABD OTH CONTRST	BW24YZZ	ICD10
CT CT SCAN OF CHEST & ABDOMEN	BW24ZZZ	ICD10
CT CT SCAN/CHEST ABDOMEN & PELVIS	BW25	ICD10
CT CT SCAN CHEST ABDOMEN & PELVIS	BW25ZZZ	ICD10
OTHER X-RAY OF THORAX	874	ICD-9
CAT OF THORAX	8741	ICD-9
ROUTINE CHEST X-RAY SO DESCRIBED	8744	ICD-9
OTHER CHEST X-RAY	8749	ICD-9
SOFT TISSUE X-RAY OF THORAX	873	ICD-9
ENDOTRACHEAL BRONCHOGRAM	8731	ICD-9
OTHER CONTRAST BRONCHOGRAM	8732	ICD-9
MEDIASTINAL PNEUMOGRAM	8733	ICD-9
SINOGRAM OF CHEST WALL	8738	ICD-9
OTHER SOFT TISSUE X-RAY CHEST WALL	8739	ICD-9
DIAGNOSTIC PROCEDURES LUNG&BRONCHUS	332	ICD-9
THORACOSCOPIC LUNG BIOPSY	3320	ICD-9
BRONCHOSCOPY THRU ARTIFICIAL STOMA	3321	ICD-9
FIBER-OPTIC BRONCHOSCOPY	3322	ICD-9
OTHER BRONCHOSCOPY	3323	ICD-9
CLOSED BIOPSY OF BRONCHUS	3324	ICD-9
OPEN BIOPSY OF BRONCHUS	3325	ICD-9
CLOSED BIOPSY OF LUNG	3326	ICD-9
CLOSED ENDOSCOPIC BIOPSY OF LUNG	3327	ICD-9
OPEN BIOPSY OF LUNG	3328	ICD-9
OTHER DIAGNOSTIC PROC LUNG/BRONCHUS	3329	ICD-9