Electronic Supplementary Material

A decision-analytic model to assess the cost-effectiveness of etelcalcetide vs cinacalcet

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Appendix 1: Extrapolation approach

The baseline-covariate adjusted EVOLVE analyses have demonstrated that the parathyroid hormone (PTH) reduction due to calcimimetic treatment reduces the incidence of mortality, cardiovascular events, fractures and parathyroidectomy (PTx) (Belozeroff et al. 2015). In a head-to-head trial the novel calcimimetic etelcalcetide furthermore has shown to be more effective in achieving PTH reduction (Block et al. 2017a). We make the assumption that this superiority on PTH reduction also translates into reduced event rates. For extrapolation we used the ability to reduce PTH from baseline by more than 30%, as this was the pre-specified primary endpoint of the etelcalcetide trials (Block et al. 2017a, Block et al. 2017b). Pooled over all three etelcalcetide trials (Table A1), 72.1% of the etelcalcetide-treaded subjects achieved the primary endpoint. For cinacalcet with 57.7% this proportion of subjects was significantly lower. Also for the placebo arm some subjects achieved a more than 30% PTH reduction compared to baseline: Here the endpoint was achieved in 8.9% of the subjects. Including evidence on all etelcalcetide trials was necessary, as for extrapolation also the outcomes of the placebo arm need to be considered.

Table A1: Summary of the etelcalcetide trial results

	Number of subjects	Number of subjects with primary endpoint* achieved	Share
Placebo	514	46	8.9%
Cinacalcet	343	198	57.7%
Etelcalcetide	849	612	72.1%

* Primary endpoint: PTH-reduction > 30% from baseline; numbers based on the etelcalcetide trials (Block et al. 2017a, Block et al. 2017b).

For extrapolating hazard ratios, the placebo arm serves as reference strategy: by definition the hazard ratio is equal to 1. For cinacalcet, the hazard ratio to reduce events, separately by considered endpoint, is directly taken from EVOLVE (Belozeroff et al. 2015). The extrapolation approach aims to generate hazard ratios for etelcalcetide vs placebo. Once there is an estimate

of the hazard ratio etelcalcetide vs placebo, the corresponding hazard ratio of etelcalcetide vs cinacalcet results implicitly: it derives by calculating the ratio of the hazard ratios of etelcalcetide vs placebo and cinacalcet vs placebo.

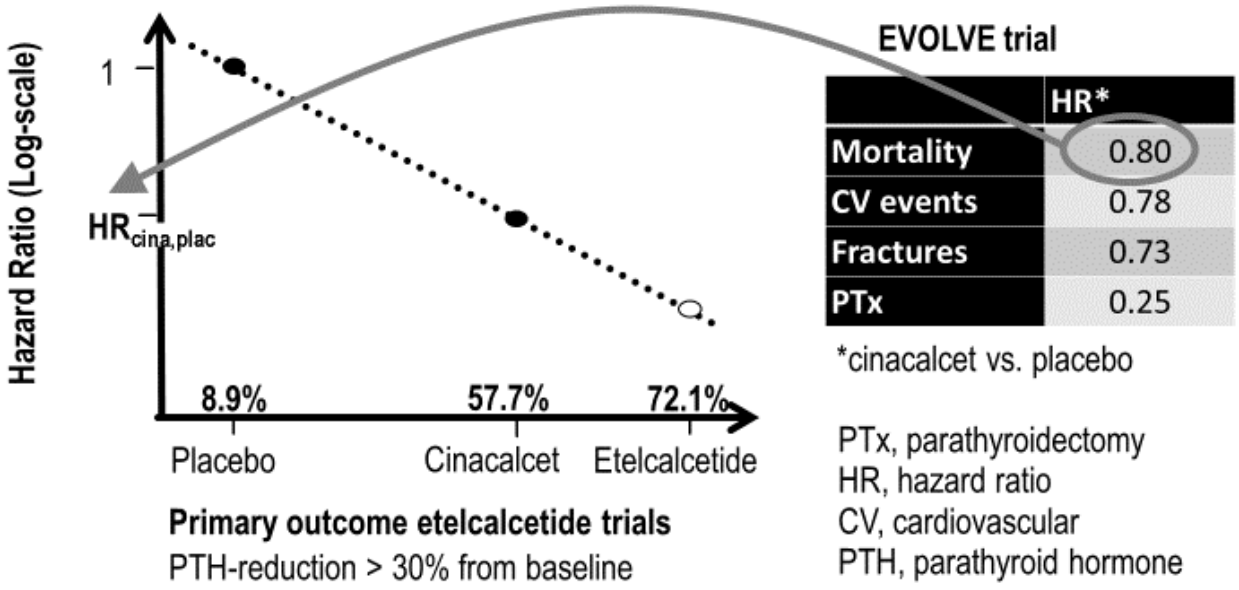

Figure A1: Illustration of the EVOLVE-based extrapolation approach to estimate treatment effects of etelcalcetide on clinical outcomes

The extrapolation approach is illustrated in Figure A1: the primary outcome of the etelcalcetide trials is used to linearly extrapolate the log hazard ratio. The log-transformation of the hazard ratio was applied, as this is a common approach to guarantee that the extrapolated hazard ratios are within the valid range, i.e. are between zero and infinity.

For the base case, as they are most consistent with the structure of the economic model, the lag-censored hazard ratios of Belozeroff et al. were used. The lag-time of 6 months has been pre-specified for EVOLVE, and was meant to account for a delayed effect after drug intake. The lag-censored hazard ratios therefore roughly correspond to the treatment effect within a persistent population.

We present a sensitivity analysis using an intention-to-treat (ITT)-based approach (covariate-adjusted). In the ITT approach, the treatment arm corresponds to a mixed average of subjects "on treatment" and subjects who discontinued treatment. To reflect the model structure, the ITT hazard ratios were disaggregated. We assumed that this disaggregation captures full treatment effect in the period prior to discontinuation. We therefore assumed that the ITT hazard ratio (HR) corresponds to a weighted average of the hazard ratio of persistent subjects and the hazard ratio of non-persistent subjects (i.e. HR=1). For weighting, we used the average

persistence within EVOLVE, which is endpoint-specific (average persistence: mortality, 59.5%; cardiovascular events, 63.4%; fractures, 61.7%; PTx, 61.5%).

Appendix 2: Persistence data

A 2.1 Overview of cinacalcet persistence data

An overview of cinacalcet persistence data is presented in Table A2. Real-world persistence data between the United States (US), Germany, France and Italy was relatively similar, ranging from a one-year persistence of 16% to 28%. In all of these studies, persistence was defined via a treatment discontinuation gap of 30 days. Substantially higher was the one-year persistence in the EVOLVE trial and in the European real-world persistence trial of Urena et al. However, Urena et al. considered subjects as persistent, if any cinacalcet dose was received on or after day 330 of follow-up. This persistence definition also covers subjects who most of the time did not take the drug - a single dose at the end of the year (day 330 to day 365) is sufficient. In EVOLVE, persistence was defined as the period until the last dose of the investigational product (IP) was received. Therefore, both Urena et al. and the EVOLVE trial tend to overestimate persistence for economic modelling purposes. For both EVOLVE and the US persistence estimates of Reams et al. the data available to the authors was sufficient for quantifying parametric distribution functions. Details are provided below.

Table A2: Real-world discontinuation data overview

Population	Sample size	One-year persistence[*]	Source
US real-world	17,763	27% (as reported)[*] 28% (parametric)[†,*]	Reams et al.
EVOLVE trial	1,938	71% (KM)[‖] 72% (parametric)[†,‖]	EVOLVE data
Germany real-world	1,835	22%[‡,*]	IMS data
Italy real-world	2,628	16%[‡,*]	IMS data
France real-world	1,215	27%[‡,*]	IMS data
Europe real-world	1,865	76%[§,*]	Urena et al.

US, United States; KM, Kaplan Meier; IMS, QuintilesIMS™, formerly known as IMS Health

[*]Discontinuation defined by a 30 day treatment gap

[†]Based on Weibull regression

[‡]IMS Health Project 1088528, Index period from Sept-2013 to Aug-2014

[§]Persistence defined as receiving any cinacalcet dose on or after day 330

[‖]Time to discontinuation of investigational product (IP is calculated as first dose of IP to IP stop data for subjects who discontinued IP for any reasons excluding death and completed IP. For subjects who completed the IP or had death, censor time to discontinuation of IP to the last IP data.

For sensitivity analysis EVOLVE persistence was applied as an upper bound, and a 1-year persistence of 16% (Weibull shape parameter from the parametric US persistence curve) as a lower bound.

A 2.2 Weibull maximum likelihood approach of US real-world persistence

Cinacalcet real-world Medicare discontinuation data was extracted from Table S4 of the supplementary appendix of Reams et al. For each one-month time interval, the number of patients at risk of discontinuation and the number of patients who discontinued during the month is shown (Table A3).

Table A3: Real-world discontinuation data based on Reams et al.

Time interval	Number of subjects at risk of discontinuation	Number of subjects who discontinued
Month 1	17,763	5,944
Month 2	11,436	1,736
Month 3	9,292	927
Month 7	5,210	345
Month 13	2,649	143
Month 19	1,491	33
Month 25	900	30
Month 37	262	5

Four standard parametric discontinuation functions were fitted via the maximum likelihood method to these data: exponential, Weibull, log-normal, log-logistic. A parametric survival function defines for each subject at risk for each time interval the probability of discontinuation. Based on the 'Akaike's information criterion' (AIC) for goodness-of-fit, the Weibull distribution was selected (Weibull: AIC = 42734; log-normal: AIC = 42749; exponential: AIC = 47224, log-logistic: AIC = 42755). The parameters of the fitted function are displayed in Table A4.

Table A4: Regression parameters of the US real-world cinacalcet discontinuation

Parametric distribution: Weibull		
Regression parameters[1]	**Point estimate**	**Standard error**
Log(shape)	-0.779	0.015
Log(scale)	1.947	0.026
Covariance matrix[2]		
	Log(shape)	**Log(scale)**
Log(shape)	0.000229	-0.000201
Log(scale)	-0.000201	0.000700

[1]The parameter estimates were derived, based on aggregated data, via the maximum likelihood approach applying the statistical software 'R', package 'stats4', function 'mle'. The parametrization corresponds to the R-function 'pweibull'. The time used for the analysis has been specified in months.

[2]The covariance matrix has been used in the probabilistic sensitivity analysis, in which alternative values for the parameters are sampled via the Cholesky decomposition method.

Example programming code for the Weibull distribution (statistical software R):
Comments regarding the usage of the maximum likelihood method:

- The observations are for each given interval and each person either a 1 (= subject discontinued) or a 0 (= subject did not discontinue).
- The likelihood of such an observation corresponds to the probability, for given Weibull parameters, that we would have observed this result. Thus for observing a 1, this is the probability of a discontinuation within the time interval, for a 0 this is the probability of not having an event.
- The likelihood of all observations simultaneously is the product of all single likelihood values.
- Using the log-likelihood is equivalent to the likelihood, but is more suitable for computational reasons.

```
# Defining the data:
time.months.vct <- c(1,2,3,7,13,19,25,37)
N.vct <- c(17763, 11436,9292,5210,2649,1491,900,262)
N.events.vct <- c(5944, 1736, 927, 345, 143, 33, 30, 5)

# Loading required packages:
library(stats4)

# The following function returns the "minus log-likelihood"

fct.log.likelihood.weib.mle <- function(log.shape, log.scale)
   {
   tmv <- time.months.vct
   events <- N.events.vct
   at.risk <- N.vct
   int.length <- 1
   return.negative.log.likelihood <- TRUE
   shape <- exp(log.shape)
   scale <- exp(log.scale)
   p.event.by.person <- (pweibull(q=tmv,shape=shape, scale=scale)-
      pweibull(q=tmv-int.length,shape=shape, scale=scale))/
        (1-pweibull(q=tmv-int.length,shape=shape, scale=scale))
   log.likelihood <- sum(events*log(p.event.by.person)) +
      sum((at.risk-events)*log(1-p.event.by.person))
   rval <- log.likelihood
   if(return.negative.log.likelihood) rval <- -log.likelihood
   return(rval)
   }

# Perform the maximum likelihood estimation
mle.results.weib <- mle(minuslogl=fct.log.likelihood.weib.mle, start =
list(log.shape=0, log.scale=0), method = "Nelder-Mead",
nobs=as.integer(sum(N.vct)), control=list(reltol=1e-25))

# Display the results
summary(mle.results.weib)
attributes(mle.results.weib)$coef
```

```
attributes(mle.results.weib)$vcov

gamma.result <- as.numeric(exp( attributes( mle.results.weib)$coef[
   "log.shape"]))
lambda.result <- as.numeric((1/exp(attributes(mle.results.weib)$coef[
   "log.scale"]))^exp(attributes(mle.results.weib)$coef["log.shape"]))

gamma.result
lambda.result

# AIC - Weibull: k=2
AIC.weib <- 2*2 + 2*attributes(mle.results.weib)$min
```

A 2.3 EVOLVE persistence data

A Kaplan-Meier plot of cinacalcet discontinuation, based on the 1938 subjects in the cinacalcet EVOLVE trial arm, is displayed in Figure A2. To achieve life-time calcimimetic persistence, alternative parametric survival functions have been fitted to these EVOLVE persistence data. According to AIC (Weibull: AIC = 7368.8, exponential: AIC = 7369.1, log-normal: AIC = 7443.5, log-logistic: AIC = 7405.6), Weibull gave the best fit (lowest AIC). The regression parameters of the selected parametric function are displayed in Table A5.

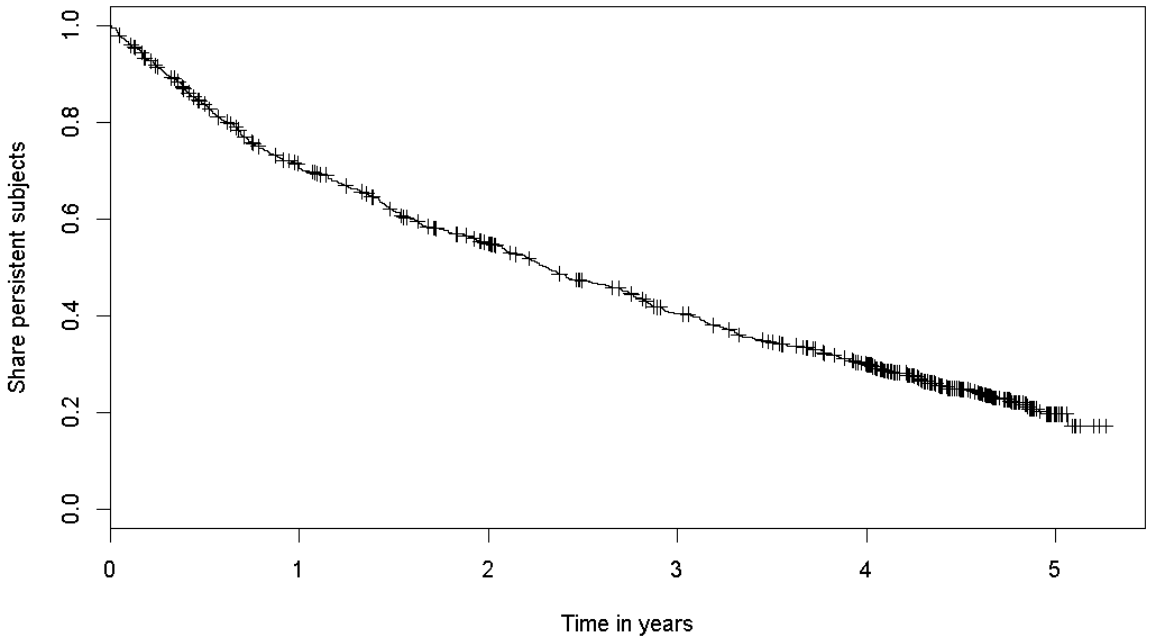

Figure A2. Discontinuation from cinacalcet based on EVOLVE.

Table A5: Regression parameters of EVOLVE cinacalcet discontinuation

Parametric distribution: Weibull		
Regression parameters[1]	**Point estimate**	**Standard error**
Intercept	3.654	0.037
Log(scale)	0.045	0.031
Covariance matrix[2]		
	Intercept	**Log(scale)**
Intercept	0.001387	0.000079
Log(scale)	0.000079	0.000938

[1]The regression parameters were derived, based on patient-level data, via the statistical software 'R', package 'survival', function 'survreg'. The time used for regression analysis has been specified in months. The software used for quantification is of relevance, as there are alternative approaches to define the parameters of the Weibull distribution. The parameterization of 'survreg' differs from the parameterization of the R function 'pweibull' as follows: survreg's scale = 1/(pweibull shape); survreg's intercept = log(pweibull scale)

[2]The covariance matrix has been used for probabilistic sensitivity analysis, where alternative parameters are sampled via the Cholesky decomposition method.

Appendix 3: Results regarding the comparator 'no calcimimetics'

The comparator 'no calcimimetics' might be appropriate for markets where cinacalcet has not yet been established, or if etelcalcetide is intended for second line calcimimetic treatment (i.e. post cinacalcet). Furthermore, all three comparators 'etelcalcetide', 'cinacalcet' and 'no calcimimetic' treatment could be assessed jointly within a full incremental analysis. The results regarding the comparator 'no calcimimetics' are displayed in Table A6 and Figure A3.

Table A6: Cost-effectiveness results regarding the comparator 'no calcimimetics'

	LYs		QALYs		Costs (discounted)		
	undiscounted	**discounted**	**undiscounted**	**discounted**	**Same WCDC**	**+15% WCDC**	**+30% WCDC**
Etelcalcetide	7.575	6.348	4.749	4.032	€14,195	€14,932	€14,251
No calcimimetics	7.319	6.144	4.565	3.882	€9,486	€9,486	€9,486
Increments							
Etelcalcetide vs no calcimimetics	0.256	0.203	0.184	0.149	€4,710	€5,447	€6,184
ICER							
Etelcalcetide vs no calcimimetics					€31,514/QALY	€36,448/QALY	€41,381/QALY

ICER, incremental cost-effectiveness ratio; LYs, life-years; WCDC, weekly calcimimetics drug costs; QALY, quality-adjusted life-year

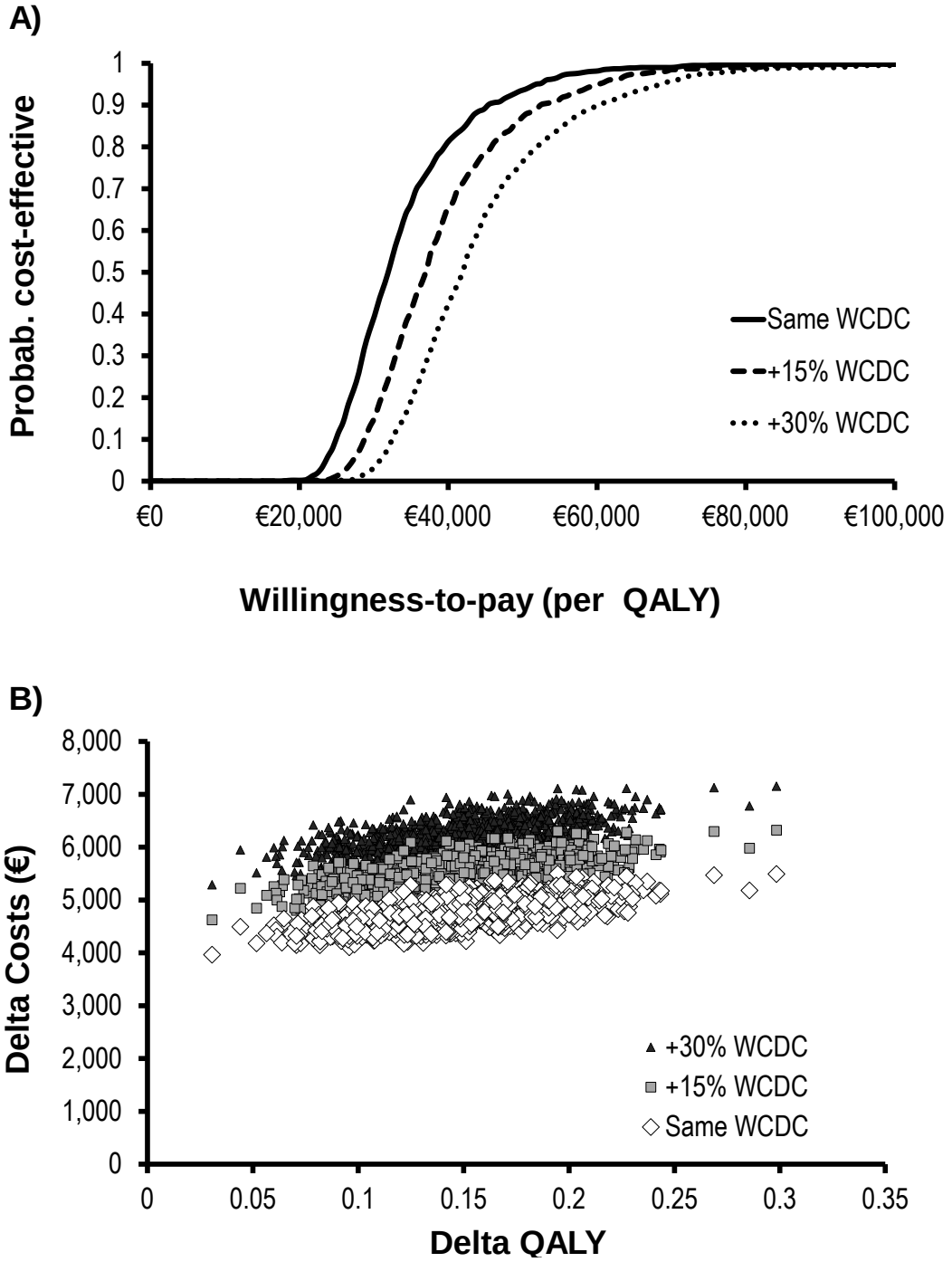

Figure A3. Results of the probabilistic sensitivity analysis of etelcalcetide vs PB/VD. A) cost-effectiveness acceptability curves; B) scatter plot of 1000 PSA iterations in the cost-effectiveness plane. WCDC: weekly calcimimetic drug cost; WTP: willingness to pay; QALY: quality-adjusted life-years.

Appendix 4: Validation

We validated the model aligned with the AdViSHE validation tool (Vemer et al. 2016). The responses to the questions of AdViSHE are as follows:

Part A: Validation of the conceptual model

A1/ Face validity testing (conceptual model): Have experts been asked to judge the appropriateness of the conceptual model?

Yes. The model has been developed in-house by Amgen (BS, VB). The face validity has been tested by clinical internal (BD, others) and external (PP, others) experts, as well as health economic experts who have experience within this area of indication (AB, RA, MA, SI). The consulted experts were consulted regularly during the model development process. The key contributors became co-authors of this publication.

A2/ Cross validity testing (conceptual model): Has this model been compared to other conceptual models found in the literature or clinical textbooks?

Yes. The conceptual model has been inspired by previous models within this area of indication, most importantly the NICE PenTAG model from Garside et al. (2007), the model from Iannazzo et al. (2012), and the model from Belozeroff et al. (2015). Details are provided in Table A7 below.

Part B: Input data validation (input data)

B1/ Face validity testing (input data): Have experts been asked to judge the appropriateness of the input data?

Yes, the same experts as in A1 were consulted (MA, RA, AB, SI, PP, BD). PP and BD are clinical experts in the field of nephrology and secondary hyperparathyroidism (SHPT). MA, SI and AB have built SHPT cost-effectiveness models in the past. RA and AB are experts regarding the requirements for NICE submissions. In case of doubt the experts were explicitly asked, which alternative input data they seek as more appropriate. The experts agree that the selected input data is appropriate, given the limitations that are discussed within the manuscript.

B2/ Model fit testing: When input parameters are based on regression models, have statistical tests been performed?

Some input parameters are based on regression models published elsewhere (i.e. utility values (Briggs et al. 2016) and cinacalcet efficacy (Belozeroff et al. 2015)). Statistical tests have been

performed. The significance of parameters has been considered, when developing the model structure. Furthermore, the parameter uncertainty has been considered within probabilistic sensitivity analysis.

Regarding discontinuation, parametric survival functions have been fitted, based on AIC to the published data (as outlined in Appendix 2 of this supplementary material).

Part C: Validation of the computerized model

C1/ External review: Has the computerized model been examined by modelling experts?

Yes, the computerized model has been examined by modelling experts (Ingress Health (http://www.ingress-health.com/), represented by Bart Heeg and Ilse van Oostrum). Furthermore, the external experts AB, MA and RA explicitly reviewed the model code. The protocol of the quality control (QC) performed by Ingress Health is stored on Amgen servers.

C2/ Extreme value testing: Has the model been run for specific, extreme sets of parameter values in order to detect any coding errors?

Yes, the QC performed by Ingress Health also includes testing the model for extreme values. All initial issues have been resolved.

C3/ Testing of traces: Have patients been tracked through the model to determine whether its logic is correct?

Yes, the Markov trace has been validated for logic correctness.

C4/ Unit testing: Have individual sub-modules of the computerized model been tested?

Yes, individual sub-modules of the computerized model have been tested. For this purpose Ingress Health has set up corresponding hypothesis. The results of this assessment are stored within the QC protocol referred to above.

Part D: Operational validation

D1/ Face validity testing (model outcomes): Have experts been asked to judge the appropriateness of the model outcomes?

Yes, the same experts as in A1 have judged the appropriateness of the model outcomes. The outcomes of the model were judged as reasonable.

Table A7: Comparison cost-effectiveness models (cross-validation)

Model aspect	**PenTAG CEM (Garside et al. 2007)**	**OPTIMA CEM (Eandi et al. 2010)**	**EVOLVE CEM (Belozeroff et al. 2015)**	**Etelcalcetide CEM**	**Rationale for Etelcalcetide CEM**
Model structure	Markov states: - Event free - CV event - Fracture event - CV event and fracture event - Event free, post CV event - Event free, post fracture - Event free, post CV, post fracture - CV death - Death other causes Transition between parallel Markov models: - Controlled - Uncontrolled - Very uncontrolled - Ineligible for surgery - Post PTx - Post PTx with adverse events	Markov states: - SHPT - SHPT + PTx - Dead CV incidence and fractures as outcome only. Patient-level simulation.	Markov states: - Event free - Non-fatal CV event - Non-fatal fracture - Post CV event - Post fracture - PTx (optionally) - Dead	Markov states: Component 1: - Event free - Post CV event - Post fracture event - Post CV, post fracture - Dead Component 2: - Calcimimetic treatment - Off calcimimetic treatment	Inspired by the previous calcimimetic cost-effectiveness models, accounting for new available evidence, and the presence of an additional comparator. With EVOLVE hard outcome data became available, and data needed to be combined across trials. Inspired by the PenTAG model and the EVOLVE CEM, mortality, CV events and fractures are covered via Markov states. In contrast to the PenTAG CEM and the Optima CEM, the Etelcalcetide CEM explicitly reports the treatment effect.
Covered types of events	Mortality (CV-related vs other); CV events; fractures; PTx	Mortality; CV events; fractures; PTx	Mortality; CV events; fractures; PTx	Mortality; CV events; fractures; PTx	Not distinguishing regarding the cause of mortality, as input

Model aspect	PenTAG CEM (Garside et al. 2007)	OPTIMA CEM (Eandi et al. 2010)	EVOLVE CEM (Belozeroff et al. 2015)	Etelcalcetide CEM	Rationale for Etelcalcetide CEM
					sources of efficacy on mortality do not distinguish either
Modelling CV events and fractures	The incidence of CV events and fractures is modelled via Markov states. When a subject has a CV event or a fracture, the subject remains for one cycle within the acute event state. Limitations: - Illustration rather complex, compared to a bridge model - Fracture and CV event cannot occur within same (3 months) cycle	CV events and fractures are captured as outcomes only. They are not modelled via Markov states. The history of events is modelled based on a patient-level simulation. Limitations: - Model cannot be run as a cohort model	The incidence of CV events and fractures is modelled via Markov states. When a subject has a CV event or a fracture, the subject remains for one cycle within the acute event state. Limitation: - No state that captures the simultaneous history of both, CV events and fractures - Subjects post CV may improve their long-term utility by having a fracture	As in the PenTAG model the simultaneous history of CV events and fractures is captured. In contrast, however, events are not modelled as a Markov state, but via a 'bridge model'.	Rationale for applying a 'bridge model': - Model structure simpler to display, without loss of accuracy - The duration of a fracture or a CV does not last for a full cycle - Allows that fracture and CV event occurs within the same cycle
Subsequent CV events and fractures	There is an increased risk of subsequent CV events and fractures. Memory captured via Markov states.	There is an increased risk of subsequent CV events and fractures. Memory captured on an individual level	There is an increased risk of subsequent CV events and fractures Memory captured via Markov states.	There is an increased risk of subsequent CV events and fractures Memory captured via Markov states.	Consistency with the PenTAG and the EVOLVE model.

Model aspect	PenTAG CEM (Garside et al. 2007)	OPTIMA CEM (Eandi et al. 2010)	EVOLVE CEM (Belozeroff et al. 2015)	Etelcalcetide CEM	Rationale for Etelcalcetide CEM
		(Patient simulation model).			
PTx	Subjects are shifted to a parallel PTx Markov model; access mortality for PTx incidence Limitation: - PTH control and the corresponding treatment effect post PTx based on 'modeller assumption', and not on empirical data	'Post PTx' is one of the three Markov states ('SHPT', 'SHPT+PTx', 'Dead'). Limitation: - Event rates post PTx taken from the literature; not connected to baseline risk.	PTx is covered as outcome only.	PTx is covered as outcome Scenario-analysis: PTx incidence not captured by the model	There is no clinical trial which would assess a potential treatment effect of PTx. In real-world subjects post PTx often continue calcimimetic treatment. PTx in EVOLVE is captured as an outcome only. A potential treatment effect of PTx is completely captured in the ITT HR estimates and at least partially captured in the lag-censored HR estimates.
Source of the treatment effect, usage of biomarkers	Modelled implicitly based on the biomarker PTH Limitations: - Treatment effect not explicitly visible - Does not consider the meanwhile published EVOLVE data - Does not consider that also Ca and P affect event incidence	Modelled implicitly based on the biomarkers PTH, Ca and P (distribution taken from OPTIMA EAP) Limitations: - Treatment effect not explicitly visible - Does not consider the meanwhile	Event-specific baseline-covariate adjusted HRs derived from the EVOLVE trial Limitation: - EVOLVE does not directly provide evidence for etelcalcetide	Efficacy explicitly modelled outside of the Markov model. Option A: Based on EVOLVE, extrapolated based on the primary endpoint of the etelcalcetide trial Option B: Modelled based on a risk prediction scheme (OPTIMA CEM), based	Study uses the best available evidence of calcimimetics on hard outcomes (i.e. EVOLVE), which was not yet available for the OPTIMA CEM and the PenTAG CEM. The OPTIMA CEM based risk-prediction scheme was used for sensitivity analysis.

Model aspect	PenTAG CEM (Garside et al. 2007)	OPTIMA CEM (Eandi et al. 2010)	EVOLVE CEM (Belozeroff et al. 2015)	Etelcalcetide CEM	Rationale for Etelcalcetide CEM
	- Parallel Markov models create model complexity	published EVOLVE data - Requires patient level simulation		on all three biomarkers PTH, Ca and P	Externalizing the phenotype calculations avoided model complexity and were preferred for transparency.
Explicitly modelling persistence	Persistence not explicitly modelled. Trial non-persistence captured implicitly (biomarkers and drug usage were taken from an ITT population) Limitations: - By using average trial persistence, the model overestimates long-term persistence - Model cannot capture an improved persistence for etelcalcetide. It thus cannot capture associated QALY gains and treatment costs.	Persistence not explicitly modelled. Trial non-persistence captured implicitly (biomarkers and drug usage were taken from an ITT population) Limitations: - By using average trial persistence, the model overestimates long-term persistence - Model cannot capture an improved persistence for etelcalcetide. It thus cannot capture associated QALY gains and treatment costs.	Persistence not modelled via Markov states, but the trial persistence has been used to determine the cinacalcet treatment costs and the long-term efficacy (down-weighting according to discontinuation). However, beyond the EVOLVE time-horizon persistence was assumed to no further decrease. Limitations: - Despite calculations based on persistence, these are not visible from the model structure	Persistence explicitly modelled. Flexibility in modelling real-world persistence, separately for both calcimimetics. If ITT-based efficacy estimates are used, these are disaggregated to reflect the model structure.	Modelling persistence explicitly was (a) necessary because input data from very different trials were combined: EVOLVE had a 5 years follow-up and therefore a much lower average persistence than the etelcalcetide trials (6 months follow-up); (b) it was expected that etelcalcetide would have a higher persistence than cinacalcet. This could not be observed in the etelcalcetide head-to-head trial, but may be relevant once further evidence becomes available.

CEM, cost-effectiveness model; EAP, efficacy assessment phase; ITT, intention-to-treat; PTH, parathyroid hormone; PTx, parathyroidectomy; HR, hazard ratio; CV, cardio-vascular; Ca, calcium; P, phosphorus; SHPT, secondary hyperparathyroidism; EVOLVE; OPTIMA; PenTAG

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